IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANTS:	Michael Maschke	CONFIRMATION NO. 7519
SERIAL NO.:	10/804,707	GROUP ART UNIT: 3737
FILED:	March 19, 2004	EXAMINER: Elmer M. Chao
TITLE:	CATHETER FOR MAGNETIC NAVIGATION	

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPELLANT'S APPEAL BRIEF

S I R:

In accordance with the provisions of 37 C.F.R. §41.37(a), Appellant herewith submits his main brief in support of the appeal of the above-referenced application.

REAL PARTY IN INTEREST:

The real party in interest is the assignee of the present application, Siemens Aktiengesellschaft, a German corporation.

RELATED APPEALS AND INTERFERENCES:

There are no related appeals and no related interferences.

STATUS OF CLAIMS:

Claims 1-4 are subject of the present appeal. All of those claims stand finally rejected in the Office Action dated April 5, 2007. Claims 1-4 constitute all pending claims of the application. No claim was added or cancelled during prosecution before the Examiner.

STATUS OF AMENDMENTS:

No Amendment was filed following the Final Rejection.

SUMMARY OF CLAIMED SUBJECT MATTER:

An example of the subject matter on appeal is set forth below with respect to independent claim 1 (which is the only independent claim on appeal), with exemplary citations to the present specification.

1. A catheter for magnetic navigation in a human body by interacting with an external magnetic field, said catheter comprising:

an elongated catheter body (catheter body 1; Fig. 1, p.3, l.7-10) terminating in a catheter tip;

a magnet disposed at said catheter tip adapted to interact with said external magnetic field to move said catheter to a desired position in a human body (magnet M_n; Figs. 1 and 2; p.3, l.14-20);

a plurality of separated, independently controllable electromagnets disposed along said catheter body (magnets M_1 and M_{10}; Fig. 1, p.3, l.10-13); and

a current supply (current supply 2 in amended Fig. 1; p.3, l.12) connected to said plurality of electromagnets to supply respective currents thereto to cause said plurality of electromagnets with current supplied thereto to exhibit respectively different magnetic moments (p.3, l.10-13).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL:

The sole issue to be reviewed on appeal is whether the subject matter of claims 1-4 would have been obvious to a person of ordinary skill in the field of designing medical catheters of the type that can be guided within the body of a patient, based on the teachings of United States Patent No. 5,845,646 (Lemelson) in

view of the teachings of United States Patent No. 6,052,610 (Koch), under the provisions of 35 U.S.C. §103(a).

ARGUMENT:

Rejection of Claims 1-4 Under §103(a) Based on Lemelson and Koch

As a basis for the rejection of claim 1 in the Final Rejection, the Examiner stated that the Lemelson reference discloses a catheter with electromagnets along a length of the catheter, however, the language of claim 1 of the present application does not merely require a plurality of magnets disposed along a length of a catheter, but requires a plurality of separated, *independently controllable* electromagnets disposed along the catheter body. This is for the purpose of giving the electromagnets respectively different magnetic moments. The electromagnets disclosed in the Lemelson reference are not individually controllable in this manner.

The only embodiment disclosed in the Lemelson patent that makes use of electromagnets is the embodiment shown in Figure 11 of that reference. As described in the paragraph beginning at column 13, line 60, that embodiment has a plurality of compartments formed in the walls of the catheter, which can contain ferromagnetic materials or strong magnets or wound electromagnets. Since the electromagnets are described as being an alternative to or equivalent of ferromagnetic materials or strong magnets, it is clear that the electromagnets are not individually controllable to respectively exhibit different magnetic moments, but are simply operated to resemble permanent magnets. This is also made clear in the remainder of that paragraph which states that a patient who is to receive the catheter is placed inside a strong, *controllable* electromagnet. Therefore, it is clear that the catheter is steered by controlling the external electromagnet, which generates a

magnetic field that interacts with the ferromagnetic material, or the electromagnets, in the respective compartments of the catheter wall.

It is true that this passage further states, at column 14, lines 3-7, that if electromagnets are used in the catheter walls, only a desired part of the catheter length can be made responsive to the externally applied magnetic field, thus making it possible to selectively shape the catheter inside the patient. The meaning of this passage is not entirely clear, but at most it would be understood by a person of ordinary skill in the field of catheter design to mean that certain of the electromagnetic could simply not be activated, while other electromagnets are activated, so as to make only a portion of the catheter length responsive to control by the external magnetic field. Obviously, any electromagnet must be capable of being turned off or on, but this trivial feature does not represent a teaching or disclosure that the electromagnets in the catheter of the Lemelson reference are individually controllable in the manner disclosed in the present application.

The fact that this passage provides no objective teaching other than simply turning individual electromagnets on and off is substantiated by the alternative that is described in the remainder of this paragraph at column 14, lines 7-11 of the Lemelson reference. As an alternative to the use of "small electromagnets," this passage states that it is possible to use a single, annular magnet or piece of ferromagnetic material that can be moved longitudinally along the interior wall of the catheter to alter the point of application of the external electromagnetic force. This makes it clear that even if "small electromagnets" are used, they are intended to resemble, as noted above, individual ferromagnets, and thus are either turned on or off, but are not individually controlled so as to give them respectively different

magnetic moments. Moreover, this passage further makes clear that the controlling mechanism is *not* currents that are individually supplied to multiple electromagnets in the catheter, but is instead control of the *external* magnetic field that is applied.

To emphasize this point, independent claim 1 was amended during prosecution to claim a current supply connected to the electromagnets, which is for the purpose of providing the aforementioned individual control. Claim 1 was amended to make clear that this individual control is not merely turning the electromagnets on and off, but is for the purpose of giving the electromagnets to which current is supplied respectively different magnetic moments. Electromagnets with such individual control to give the respective current-supplied electromagnets different magnetic moments is not disclosed or suggested in the Lemelson reference.

Even if in the Lemelson catheter some electromagnets may be turned off at certain times, while others are activated (if the aforementioned passage in the Lemelson reference is interpreted favorably to the Examiner's position, which is am interpretation that is by no means compelled by the relevant language in the Lemelson reference), this is still not a disclosure to give those different electromagnets respectively different magnetic moments. The turned off electromagnets simply have no magnetic moment at all associated therewith. A person of ordinary skill knowledgeable in the field of electromagnetism would not consider the non-activated electromagnets to have a magnetic moment of zero, whereas the activated electromagnets have a non-zero magnetic moment, because the non-activated electromagnets simply have no magnetic moment at all. Intentionally giving an electromagnet a magnetic moment of zero is something

different from simply not turning an electromagnet on. Attributing a magnetic moment of zero to a non-activated electromagnet would be the same as saying that some object composed entirely of non-magnetic material has a magnetic moment of zero. One would not say, for example, that a pencil has a magnetic moment of zero; it is meaningless to ascribe any magnetic moment at al to such an object, and the same is true of a non-activated electromagnet.

Moreover, claim 1 states that it is the electromagnets to which a current is supplied that have the respectively different magnetic moments, thereby precluding a non-activated electromagnet from corresponding to the language of claim 1.

The Examiner relied on the Koch reference as teaching a catheter having magnet at its tip, since the Examiner acknowledged that the Lemelson et al reference does not explicitly disclose a catheter having a magnet at the tip thereof. For the above reasons, however, in view of the aforementioned discussion of the catheter disclosed in the Lemelson reference, even if that catheter disclosed in Lemelson were modified to provide it with a magnet at its tip, the subject matter of claim 1 still would not result.

In the Final Rejection, in response to the above arguments that were made during prosecution, the Examiner emphasized the statement at column 14, lines 3-7 in the aforementioned passage in the Lemelson patent, that the catheter may be "selectively shaped" when using electromagnets disposed along the catheter wall. The Examiner stated that a person of ordinary skill in the relevant technology would not at most interpret this language to mean the limited ability of only turning the electromagnets on or off. The Examiner stated that, due to the perennial desire for the precise navigation of in vivo catheters, a person of ordinary skill would certainly

interpret this passage to include driving the electromagnets at different current levels to induce different magnetic moments within the catheter, thereby causing precise shaping of the catheter. The Examiner stated a person with knowledge of the relationship between the amount of current fed to an electromagnet, and the corresponding magnetic moment, would surely regard "Lemelson's invention" to imply the use of different non-zero current levels in light of the language at column 14, lines 6-7 ("...making it possible to selectively shape the catheter inside the patient."

In response, Appellant respectfully submits that this argument not only begs the question of obviousness, but is actually evidence of the non-obviousness of the subject matter on appeal. It goes without saying that those of ordinary skill in the relevant technology are knowledgeable with regard to the interaction of magnets, whether ferromagnets or electromagnets, with an externally applied magnetic field. The aforementioned statements noted by the Appellant in the relevant passages in the Lemelson reference, however, make clear that, *as disclosed in that reference*, individual control of electromagnets to give those electromagnets respectively different magnetic moments was not realized by the inventor in the Lemelson reference as being a way to guide the catheter through the body while applying an external magnetic field. The statements noted by the Appellant makes clear that the only "control" that was disclosed in the Lemelson reference is to adjust the *externally applied* magnetic field for guidance purposes. A limited amount of selective shaping of the catheter can be accomplished, as noted by the Examiner, by augmenting that control with the use of multiple electromagnets, instead of ferromagnets, but the aforementioned alternative of using only a single electromagnet *or ferromagnet*

makes clear that even when such selective shaping is undertaken, it is done solely by making the electromagnets *responsive* (by individually activating them) or non-responsive (by individually not activating them), rather than by applying individually adjustable or controllable currents to the respective electromagnets, so as to give them respectively different magnetic moments.

Appellant respectively submits this position of the Examiner is also shaded by the scope of the term "magnetic moment" that the Examiner contends would be evident to those of ordinary skill in the art. Using the above-noted example of a pencil, Appellant respectfully submits that if the Examiner had been shown a pencil, before reading Appellant's application disclosure, and were asked whether the pencil exhibits a magnetic moment, the Examiner would have either said the question is meaningless or non-understandable, or would have simply answered "no." Appellant respectfully submits that if the Examiner objectively places himself in a frame of mind prior to reading Appellant's disclosure, the Examiner would not have answered such a question by stating that the pencil has a "magnetic moment of zero." In the general context of engineering and science, giving something a physical property that has a value of zero is considered to be an intentional, controllable act, since a value of zero must still be set and somehow measured.

The same is true of a non-activated electromagnet which, when non-activated, has the same status as a pencil or any other inanimate object.

The Federal Circuit stated in *In re Lee* 227 F.3d 1338, 61 U.S.P.Q. 2d 1430 (Fed. Cir. 2002):

> "The factual inquiry whether to combine references must be thorough and searching. ...It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with."

Similarly, quoting *C.R. Bard, Inc. v. M3 Systems, Inc.,* 157 F.3d 1340, 1352, 48 U.S.P.Q. 2d 1225, 1232 (Fed. Cir. 1998), the Federal Circuit in *Brown & Williamson Tobacco Court v. Philip Morris, Inc.,* 229 F.3d 1120, 1124-1125, 56 U.S.P.Q. 2d 1456, 1459 (Fed. Cir. 2000) stated:

> [A] showing of a suggestion, teaching or motivation to combine the prior art references is an 'essential component of an obviousness holding'.

In *In re Dembiczak,* 175 F.3d 994,999, 50 U.S.P.Q. 2d 1614, 1617 (Fed. Cir. 1999) the Federal Circuit stated:

> Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.

Consistently, in *In re Rouffet,* 149 F.3d 1350, 1359, 47 U.S.P.Q. 2d 1453, 1459 (Fed. Cir. 1998), the Federal Circuit stated:

> [E]ven when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill in the art, that suggests the claimed combination. In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.

In *Winner International Royalty Corp. v. Wang,* 200 F.3d 1340, 1348-1349, 53 U.S.P.Q. 2d 1580, 1586 (Fed. Cir. 2000), the Federal Circuit stated:

> Although a reference need not expressly teach that the disclosure contained therein should be combined with another, ... the showing of combinability, in whatever form, must nevertheless be clear and particular.

Lastly, in *Crown Operations International, Ltd. v. Solutia, Inc.,* 289 F.3d 1367, 1376, 62 U.S.P.Q. 2d 1917 (Fed. Cir. 2002), the Federal Circuit stated:

> There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor.

Appellant is, of course, aware of the recent decision of the United States Supreme Court in *KSR International Co. v. Teleflex, Inc.*, ___ U.S. _____, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385 (2007). That decision has received a considerable amount of inaccurate publicity to the effect that the decision allegedly does away with the requirement to find a "teaching, suggestion or motivation" explicitly in the prior art of record in order to substantiate a rejection or an invalidity argument based on 35 U.S.C. §103(a). Appellant submits the *KSR* decision does not stand for such a proposition, and in fact endorses and approves of the requirement for vigorously substantiating an obviousness argument with detailed evidence. The *KSR* decision, however, recognized that the level of detail must not be rigidly and inflexibly set, and the Supreme Court recognized that there will undoubtedly be situations wherein the distinction between the claimed subject matter and the prior art is so minimal that a relaxed evidentiary argument will suffice. Even after the *KSR* decision, however, it is clear that an obviousness rejection can never be based on speculation, nor can it be based on a substitution of the Examiner's opinion in opposition to clear statements in the prior art that tend to support a non-obviousness conclusion, rather than an obviousness conclusion.

In order to dispel the notion that the *KSR* decision somehow gives license to an obviousness rejection that fails to identify a teaching, motivation or suggestion in the prior art, it is worth quoting several passages from the *KSR* decision at length.

At 127 S.Ct. 1740, after discussing the earlier Supreme Court decisions in *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969) and *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976), the Supreme Court in the *KSR* decision stated:

> The principles underlying these cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida* and *Anderson's-Black Rock* are illustrative - a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

The Supreme Court then made the following extremely important statement, which is highly relevant to assessing the obviousness of the subject matter in the present appeal:

> Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another, or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands know to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take into account the influences and creative steps that a person of ordinary skill in the art would employ.

As to the reliance on the requirement for demonstrating a teaching, suggestion or motivation in the prior art of record, the Supreme Court stated at 127 S.Ct. 1741

> When it first established the requirement of demonstrating a teaching, suggestion or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight.

The Supreme Court then stated at 127 S.Ct. 1741 that the Court of Customs and Patent Appeals and the United States Court of Appeals for the Federal Circuit have *no doubt* applied the requirement for a teaching, motivation or suggestion to be identified in the prior art in accord with the principles discussed in the *KSR* decision. The Supreme Court stated there is "no necessary inconsistency" between the idea underlying the requirement for a teaching, motivation or suggestion, and the analysis required by *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The Supreme Court, as noted above, cautioned only against transforming this general principle into "a rigid rule that limits the obviousness inquiry."

Appellant respectfully submits that the Examiner has not satisfied the rigorous evidentiary standards relating to identification of a teaching or guidance in the prior art with respect to the subject matter of claim 1 of the present application, and Appellant further submits that the only location where such guidance is present is Appellant's disclosure, on which Appellant respectfully submits the Examiner has impermissibly relied. Nothing in the *KSR* decision alleviates this error of law.

For the above reasons, therefore, Appellant respectfully submits that the subject matter of claim 1 would not have been obvious to a person of ordinary skill in the relevant technology under the provisions of 35 U.S.C. §103(a), based on the teachings of the Lemelson and Koch references. Claims 2, 3 and 4 add further

structure to the non-obvious combination of claim 1, and therefore would not have been obvious to such a person of ordinary skill for the same reasons discussed in connection with claim 1.

CONCLUSION:

All claims of the application are therefore submitted to be in condition for allowance. Reversal of the above rejection is proper, and the same is respectfully requested.

This Appeal Brief is accompanied by a electronic payment of the requisite fee in the amount of $500.00.

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CLAIMS APPENDIX

1. A catheter for magnetic navigation in a human body by interacting with an external magnetic field, said catheter comprising:

an elongated catheter body terminating in a catheter tip;

a magnet disposed at said catheter tip adapted to interact with said external magnetic field to move said catheter to a desired position in a human body;

a plurality of separated, independently controllable electromagnets disposed along said catheter body; and

a current supply connected to said plurality of electromagnets to supply respective currents thereto to cause said plurality of electromagnets with current supplied thereto to exhibit respectively different magnetic moments.

2. A catheter as claimed in claim 1 wherein said magnet at said catheter tip is a permanent magnet.

3. A catheter as claimed in claim 1 wherein said magnet at said catheter tip is an electromagnet.

4. A catheter as claimed in claim 1 wherein said current supply supplies said plurality of electromagnets with respective synchronously-clocked currents.

EVIDENCE APPENDIX

Exhibit A: Figs. 1 and 2 - Presented in amended form in Amendment "A" filed December 26, 2006.

Exhibit B: United States Patent No. 5,845,646 (Lemelson) - Cited in Office Actions dated July 21, 2006 and April 5, 2007.

Exhibit C: United States Patent No. 6,052,610 (Koch) - Cited in Office Actions dated July 21, 2006, and April 5, 2007.

RELATED PROCEEDINGS APPENDIX

None.

CH1\ 5189831.1

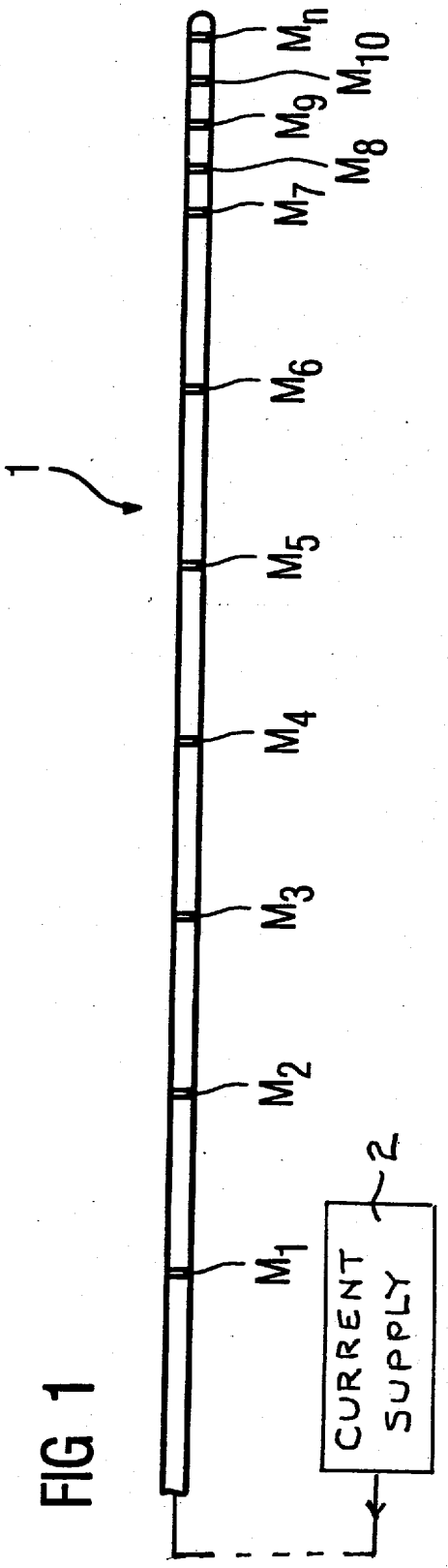

FIG 1

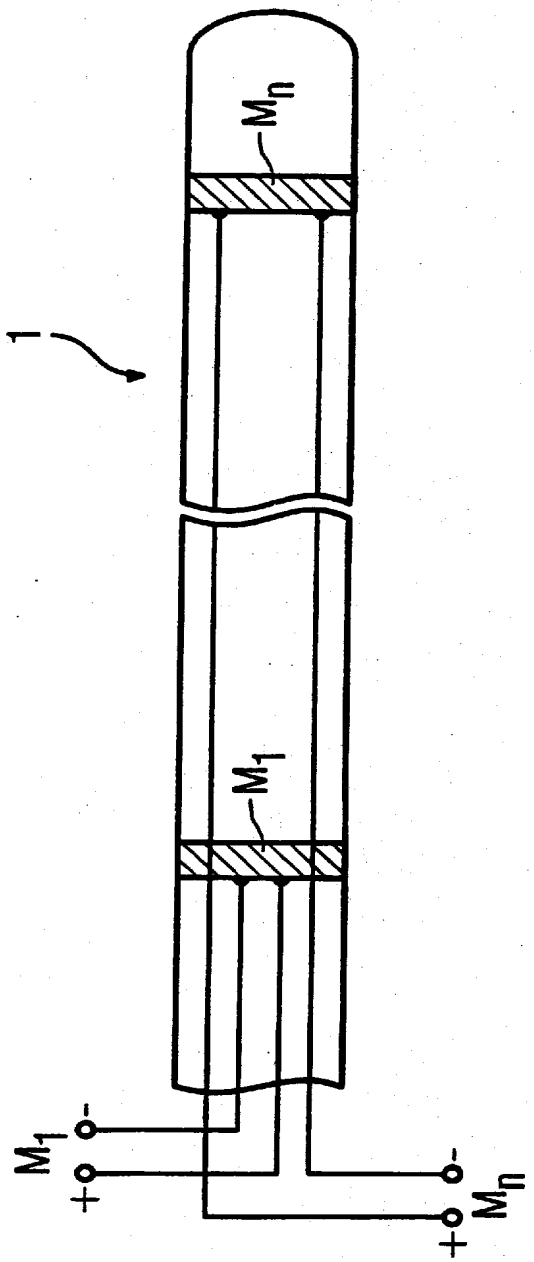

FIG 2

US005845646A

United States Patent [19]

Lemelson

[11] **Patent Number: 5,845,646**

[45] **Date of Patent: Dec. 8, 1998**

[54] **SYSTEM AND METHOD FOR TREATING SELECT TISSUE IN A LIVING BEING**

[76] Inventor: **Jerome Lemelson**, 930 Tahoe Blvd. Unit 802, Suite 286, Incline Village, Nebr. 89541-9436

[21] Appl. No.: **743,794**

[22] Filed: **Nov. 5, 1996**

[51] **Int. Cl.**[6] **A61M 5/00**

[52] **U.S. Cl.** **128/899**; 604/95; 604/21

[58] **Field of Search** 128/653.1, 653.2, 128/721, 897, 898, 899, 665; 378/41, 42, 62, 63; 604/164, 93, 264, 280, 21, 281, 95; 252/500; 285/261; 600/407, 410

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Primary Examiner—Marvin M. Lateef
Assistant Examiner—Eleni Mantis Mercader
Attorney, Agent, or Firm—Niro, Scavone, Haller & Niro

[57] **ABSTRACT**

A catheter suitable for directing a measured aliquot of liquid drug to a specific target location in the body having a reservoir containing a premeasured aliquot of liquid drug which is positioned near the end of catheter. The reservoir is attached to the distal end of an extendable member, which is used to extend the hollow needle into the tissue surrounding the distal end of the catheter through an orifice.

8 Claims, 6 Drawing Sheets

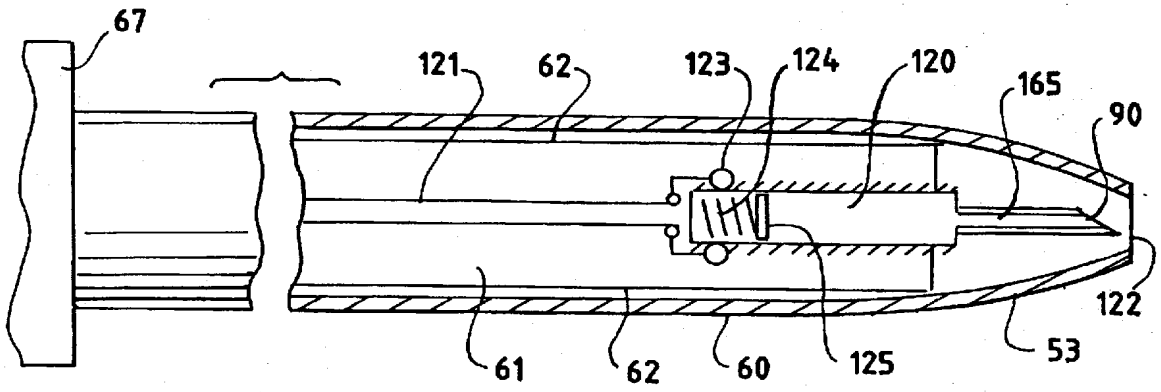
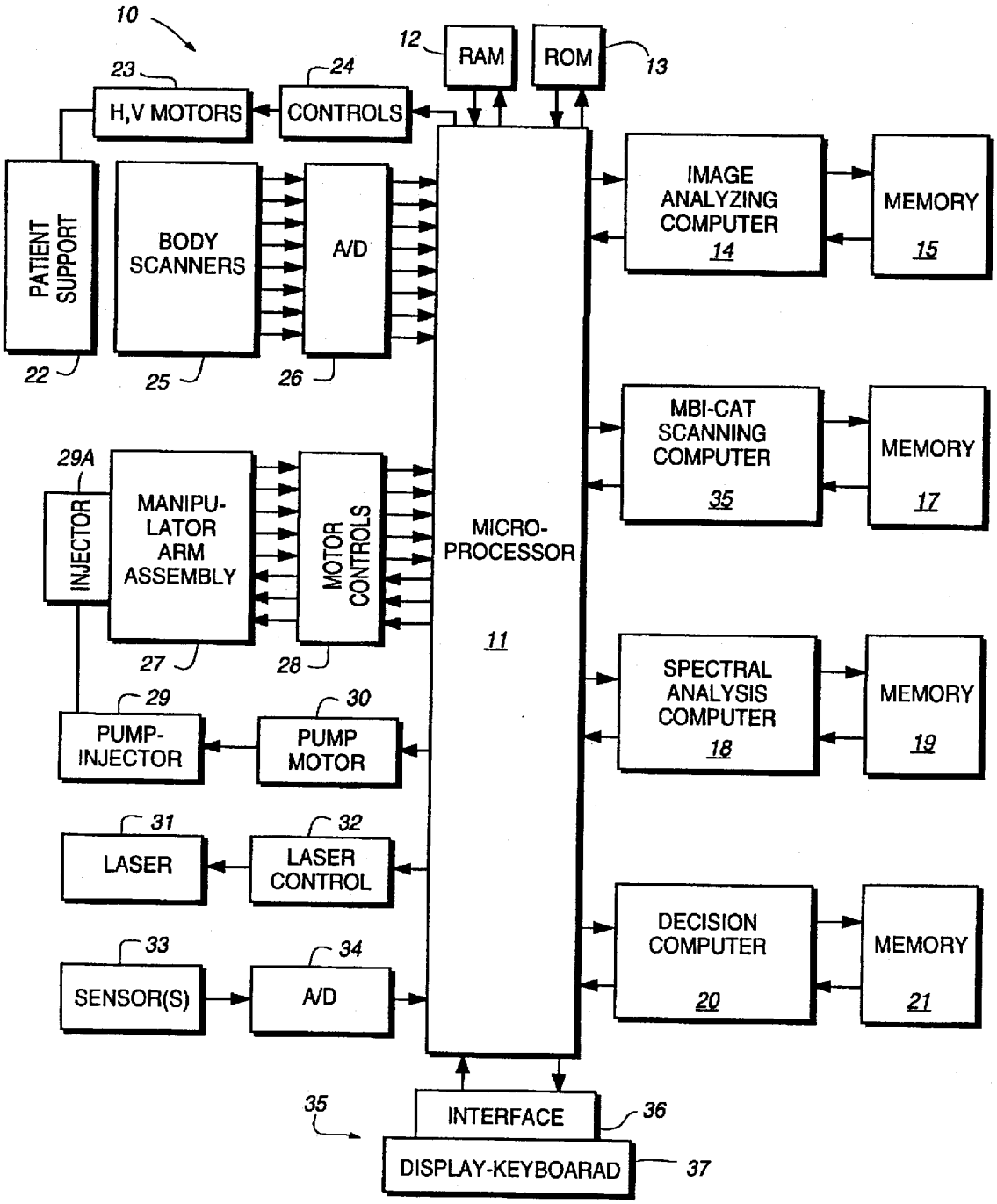


FIG. 1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12
RAM
ROM
13
23
H,V MOTORS
24
CONTROLS
PATIENT SUPPORT
22
BODY SCANNERS
25
A/D
26
IMAGE ANALYZING COMPUTER
14
MEMORY
15
MBI-CAT SCANNING COMPUTER
35
MEMORY
17
29A
INJECTOR
MANIPU-LATOR ARM ASSEMBLY
27
MOTOR CONTROLS
28
MICRO-PROCESSOR
11
SPECTRAL ANALYSIS COMPUTER
18
MEMORY
19
29
PUMP-INJECTOR
30
PUMP MOTOR
31
LASER
32
LASER CONTROL
DECISION COMPUTER
20
MEMORY
21
33
SENSOR(S)
34
A/D
35
INTERFACE
36
DISPLAY-KEYBOARAD
37

FIG. 2

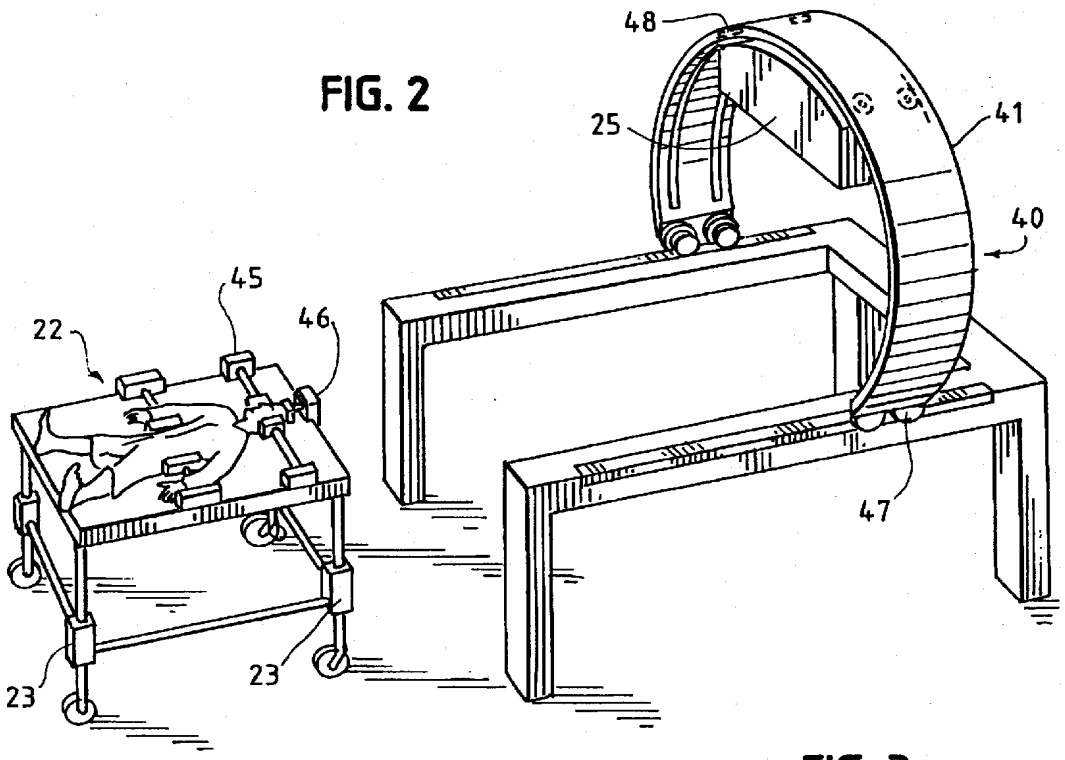


FIG. 3

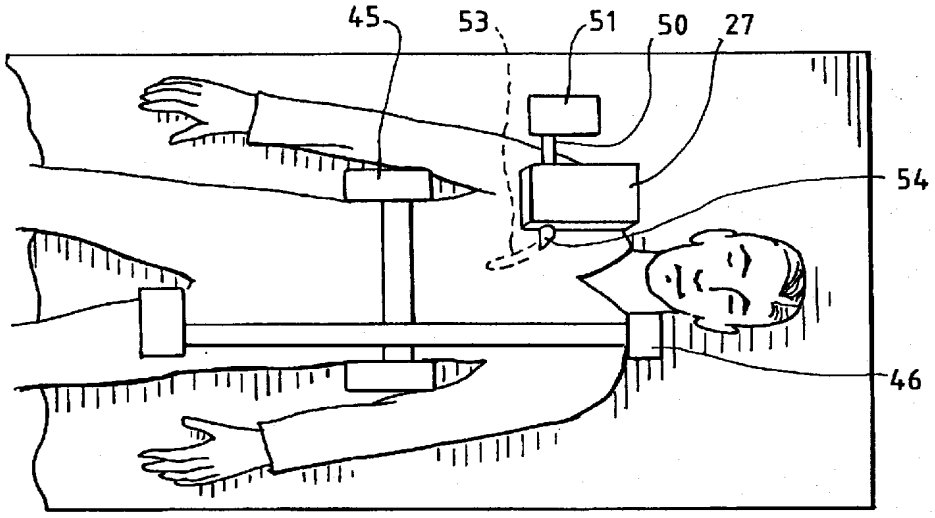


FIG. 4

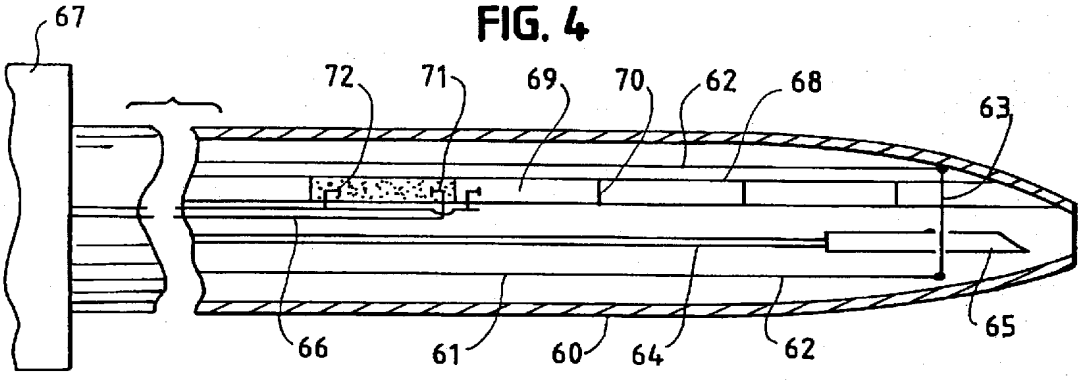


FIG. 5

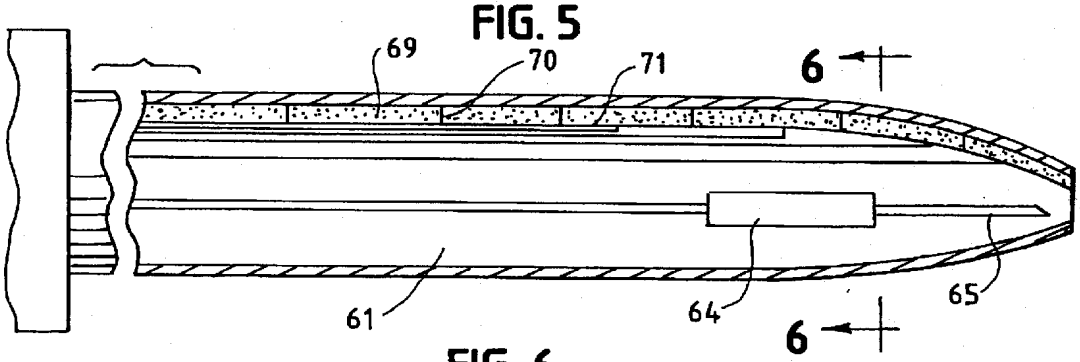


FIG. 6

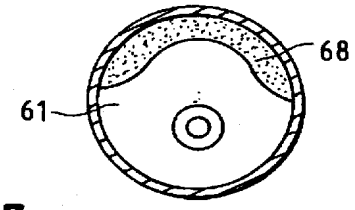


FIG. 7

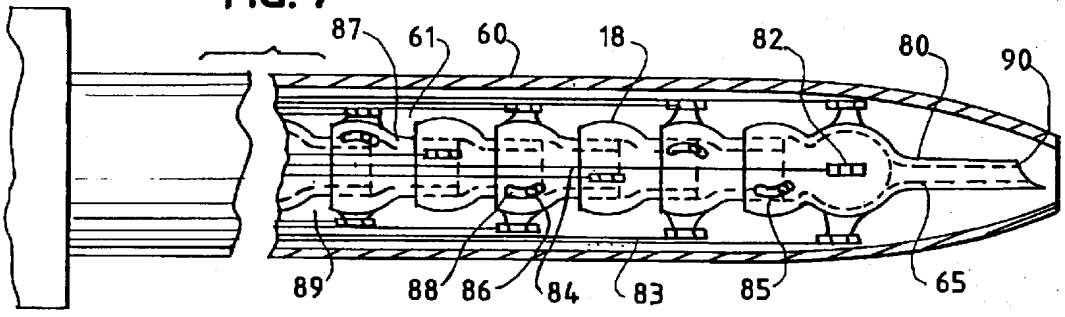


FIG. 8

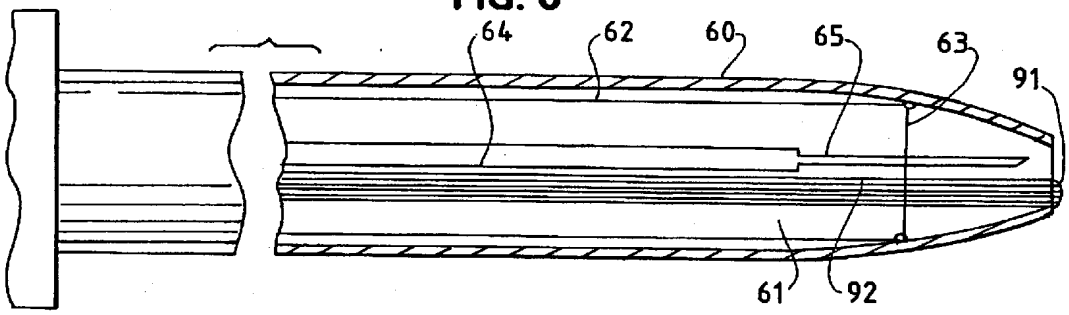


FIG. 9

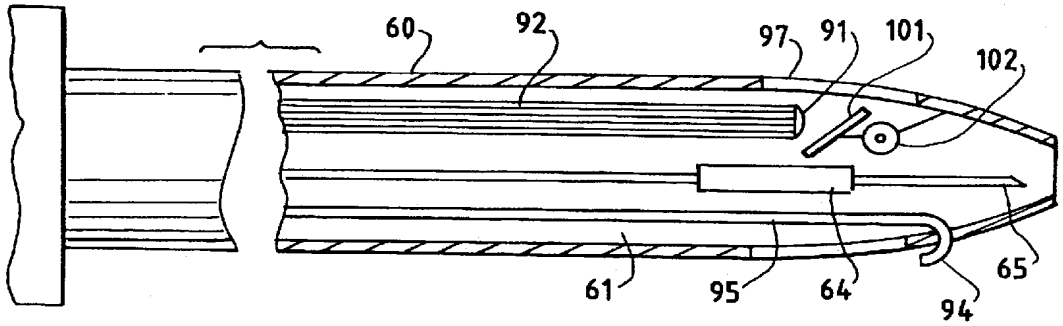


FIG. 10

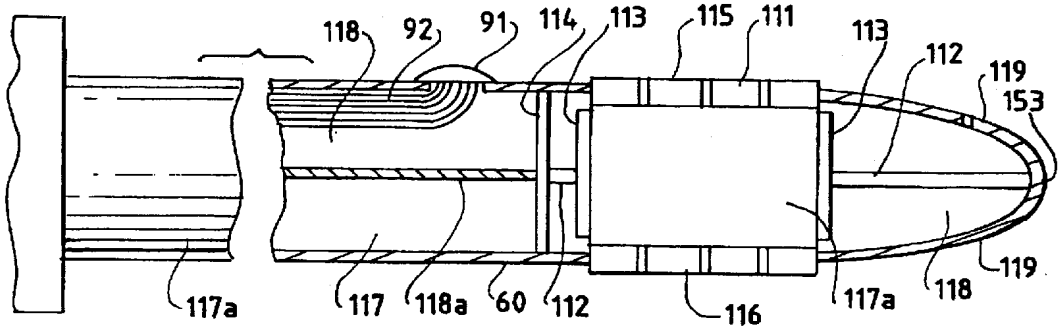


FIG. 11

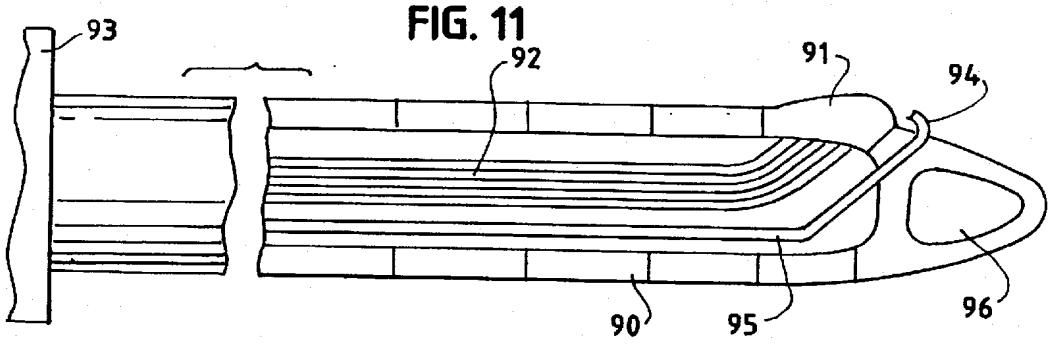


FIG. 12

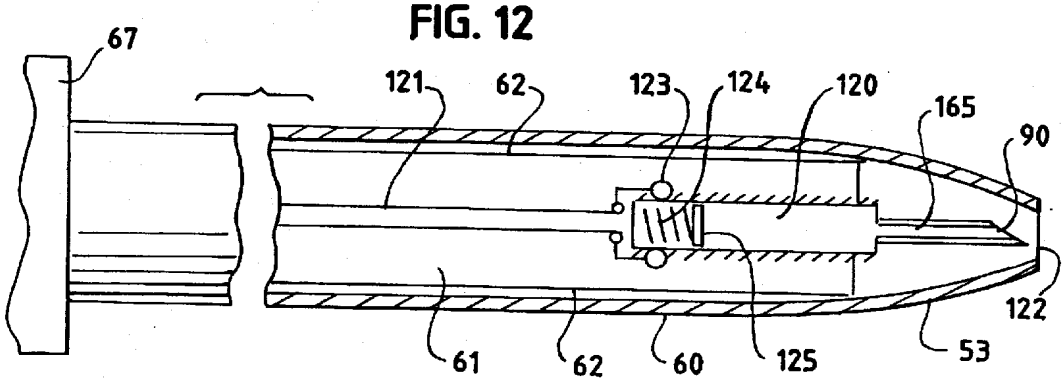


FIG. 13

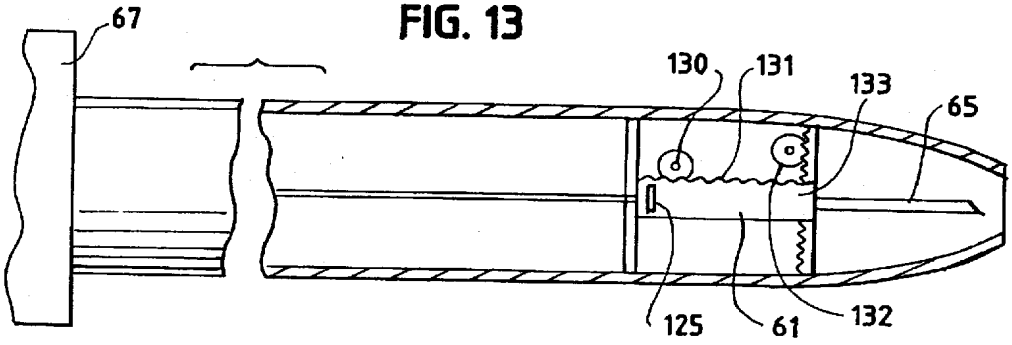


FIG. 14

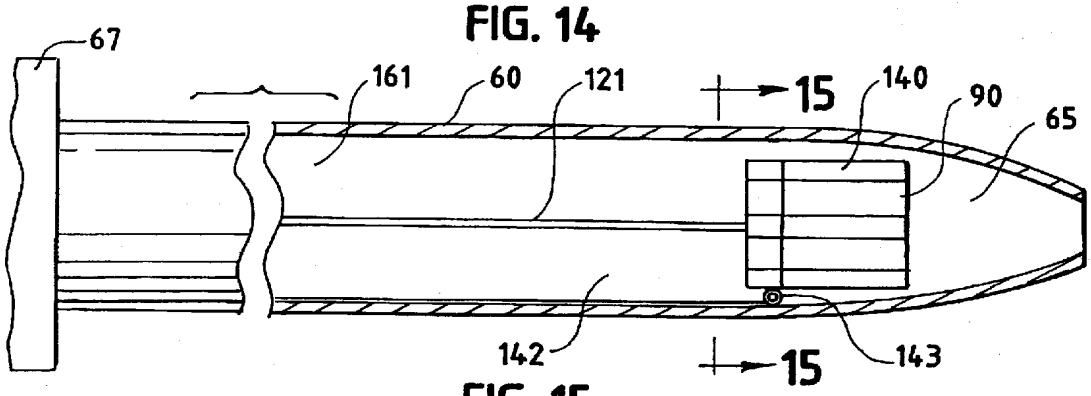


FIG. 15

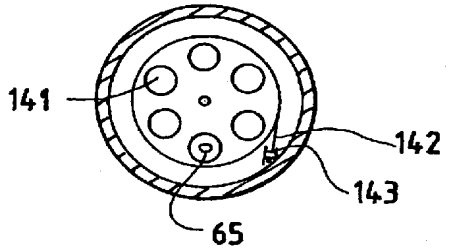


FIG. 16

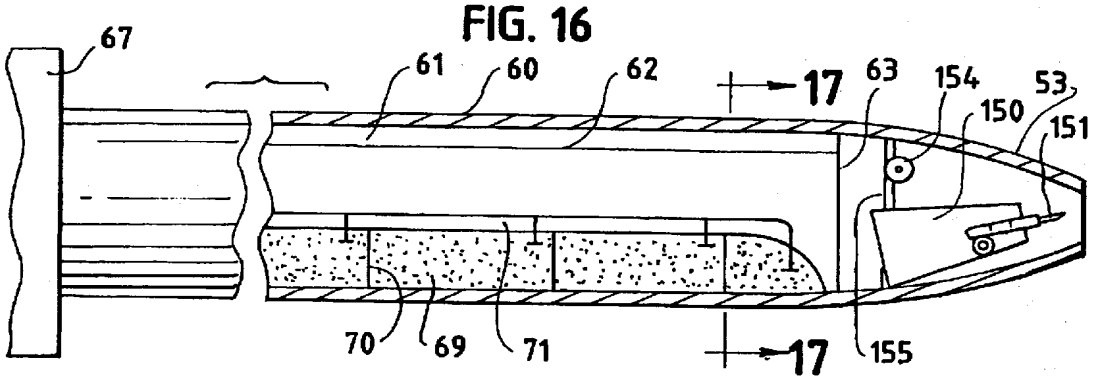
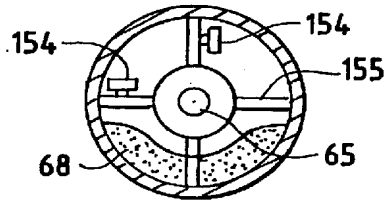


FIG. 17



SYSTEM AND METHOD FOR TREATING SELECT TISSUE IN A LIVING BEING

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to systems for endoscopic treatment of select tissue in living beings (humans or animals) using real-time computer control to visualize, to position and (if desired) to operate drug dispensing, sampling (biopsy); imaging, testing and/or treatment devices within the body of the patient. The invention employs a computerized imaging system (such as CAT scan, MRI imaging, ultrasound imaging, infrared, X-ray, UV/visible light fluorescence, Raman spectroscopy or microwave imaging) to sense the position of an endoscopic treatment system within the body; and, in a preferred embodiment, provides real-time computer control to maintain and adjust the position of the treatment system and/or the position of the patient relative to the treatment system; and also providing (if desired) real-time computer control of the operation of the treatment system itself. Types of treatment systems suitable for use in the invention include surgical tools and tissue manipulators, devices for in vivo delivery of drugs in solid or liquid form; angioplasty devices; biopsy and sampling devices; devices for delivery of RF, thermal, microwave or laser energy or ionizing radiation; and internal illumination and imaging devices, such as modified catheters, endoscopes, laparoscopes and the like instruments, or a combination thereof.

Background of the Invention

A variety of endoscopic treatment devices exist, including those containing viewing or imaging systems; devices for endoscopic surgery (such as laser angiosurgery, as in U.S. Pat. No. 5,496,305 (Kittrell, et al.)); biopsy devices and drug delivery systems such as my U.S. Pat. No. 4,900,303 and U.S. Pat. No. 4,578,061. Typically, however, such systems are designed to be manually deployed and positioned by a surgeon and assistants. Surgical personnel must not only treat the patient (i.e., perform the surgical procedure; interpret the images or diagnostic data or obtain the biopsy sample) but also simultaneously maintain the endoscopic device such as a catheter in position (sometimes with great precision) and operate any mechanisms in the device as well, all manually working through a catheter support tube assembly which, desirably, should be as small in diameter as possible to minimize trauma during insertion and operation.

In many diagnosis and treatment situations, precise, real-time positioning of the distal (working) end of the catheter is the key to success with delivering microdoses of drugs that may have high toxicity (e.g. chemotherapeutic agents) as well as directing ionizing radiation or microwaves precisely at the tissue to be altered or destroyed, while minimizing trauma to surrounding, healthy tissue. Precise control of position is also useful in sampling (biopsy) situations to allow samples to be taken from the correct locations within the body.

Nevertheless, internal steering mechanisms for catheters (not to mention real-time control of their position within the body, which is effectively unknown) have been comparatively crude. Catheters, endoscopes, etc. have to be very long and thin, and usually are rather stiff (at least over part of their lengths) to enable them to be advanced through body ducts or directly into tissue without buckling. (Sometimes a removable "split sheath" introducer is used during implantation, and is then split and pulled away from around the catheter, leaving a very pliable catheter in place but incapable of further forward advancement. But, such pliable catheters typically cannot be steered at all, once in place, except for some limited rotation from the outside of the body.)

Steerable or positionable catheters typically are rather stiff (and correspondingly traumatic). They may use one or more off-axis pull wires to deflect the distal tip of the catheter by 20° or 30°. The pull wire or wires are fixed at the distal tip of the catheter and extend back to the proximal end. When pulled, they generate off-axis longitudinal forces that deflect the tip toward the side of the catheter where the wire is being pulled. Sometimes, as in U.S. Pat. No. 5,531,677 (Lundquist), only one off-center pull wire is used, in combination with a stiff backbone 180° away, and ribs that make the torque tube preferentially flexible toward the pull wire. (See FIG. 5 of the '677 patent; the pull wire is at reference numeral 48; the backbone is at 32 and the slots 30 between the ribs produce preferential flexibility, creating the arc shown when the wire is pulled. Return forces may be provided by an internal coil spring.)

Another system is shown in U.S. Pat. No. 5,531,687 (Snoke, et al.). In that reference, two diametrically opposed pull wires 201 and 202 are wrapped around a central drum or wheel in the handle; rotation of the wheel produces deflection at the tip towards whichever wire is pulled. This permits some limited tip movement in either of two opposite directions (though not in any intermediate directions).

U.S. Pat. No. 4,983,165 (Loiterman) uses an internal guide wire (for stiffness and to prevent buckling) in combination with a plurality of externally-inflatable pouches to force the distal end of a catheter towards (or away from) one wall of a body duct. See FIGS. 4–6 of the Loiterman '165 patent. This arrangement allows the user of a catheter which is passing through a body duct to select one branch of the duct. Such an arrangement would not be usable, however, for a catheter advancing through soft tissue.

U.S. Pat. No. 5,545,200 (West) shows another pull-wire arrangement, in which the pull wire 58 is opposed by a longitudinally-advancable "stiffener member 68" (see FIGS. 3A and 3B). By longitudinally advancing or retracting the stiffener member, the point where curvature begins can be adjusted.

Another approach to adjusting the point of curvature is shown in U.S. Pat. No. 5,533,967 (Imran). The Imran patent shows a central shape-memory element 57 which is made of a shape-memory material, such as Nitinol, which straightens out when heated (as by direct electrical resistance heating) and which is more flexible when not heated. Imran discloses moving an annular "selective conductive bypass means 66" longitudinally along the shape-memory element. Where the bypass means covers (and electrically contacts) the shape memory element, current flows through the bypass rather than through the memory element. In that region, therefore, there is less or no electrical heating and that part of the shape memory element is very flexible. Thus, when one or more pull wires are actuated, the point of flexure occurs at the place where the bypass means has been positioned. Imran also suggests that a plurality of elongate elements 41–43 "having a negative coefficient of [thermal] expansion" could be used in place of moving pull wires to generate the forces needed to cause tip deflection.

Similarly, catheters that are used for imaging typically also must be introduced and positioned manually. Moreover, they lack facility for independently rotating or positioning the sensing or imaging element independently of the

manipulating or treatment device in order to focus on a specific area of tissue being treated by drugs, mechanical manipulation or other means. U.S. Pat. No. 5,435,805 (Edwards, et al.), for example, discloses various embodiments of a probing head and, in one embodiment, dual optical lenses (see FIG. 8). Embodiments in FIGS. 15–20 show a needle-like element that is termed a "stylet" or "stylus" for penetrating tissue, such as a prostate, to apply microwave or RF treatment. At column 6, lines 56–60, it is stated that the device can be used in a variety of ways including to deliver liquid (i.e., drug). Positioning of the overall catheter is manual, by means of a torque tube assembly.

U.S. Pat. No. 4,967,745 (Hayes, et al.) discloses a polished end fiber optic cable bundle that forms a lens. A computer control system is adapted to locate healthy or diseased tissue using spectral imaging techniques, and to control a laser to fire pulses of laser radiation down one or more optical fibers to destroy arterial plaque while avoiding damage to healthy tissue. Inflatable balloons inside the catheter, or control wires, may be used to deflect the fiber optic bundle within the catheter. The catheter itself, however, is manually introduced and positioned.

Still further techniques for steering a catheter within the body by altering its shape are disclosed in my co-pending application Ser. No. 08/662,345 (filed Jul. 12, 1996), the disclosure of which is incorporated herein by reference. These techniques utilize electrosensitive gels to alter the rigidity or shape of a catheter.

The prior art approaches, however, are deficient in a number of particulars. They require not only manual introduction, but also more or less constant manual adjustment of position and often of operation. Almost everything is done by hand: the surgeon works by feel, with rudimentary or no imaging capability to guide him and no active computer control to take over so he can concentrate on the operation instead of positioning the catheter and keeping it in position. This increases the number of surgical personnel required, and distracts them from the procedure or diagnosis in progress.

Prior art devices typically also reflect the premise that forces used to alter the shape of the catheter have to be generated and exerted from within the lumen or lumens of the catheter itself (such as by pull wires). Since catheters, endoscopes and other devices, for use inside the body are usually long and thin. This automatically creates problems in obtaining a favorable mechanical advantage for forces that one wants to exert normal to the axis. (In other words, it is necessary to pull the wire(s) very hard in order to generate only a moderate amount of sideways force, since the fulcrum point typically is far back from the area where a bend is desired.)

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows one type of computer control system suitable for real-time positioning of an endoscopic treatment or diagnosis system (such as a catheter) within the body.

FIG. **2** shows a patient orientation system which optionally can be used to help control the position of the endoscopic device within the body.

FIG. **3** shows further detail of a patient orientation system which optionally can be used to help control the position of the endoscopic device within the body.

FIG. **4** shows a steerable catheter system (which can utilize real-time external computer imaging control system to find and maintain a position in the body adjacent the volume of tissue to be diagnosed or treated) wherein a steering mechanism for the catheter uses pull wires combined with an electrically-controllable stiffening member using an electrorheological gel.

FIG. **5** shows an alternative arrangement of a steerable catheter using an electrorheological gel.

FIG. **6** shows a cross-sectional view of the steerable catheter of FIG. **5**.

FIG. **7** illustrates a steerable hollow needle mechanism suitable for injecting drugs, which can be introduced through a pliable catheter.

FIG. **8** shows a steerable catheter system utilizing real-time computer control based on internal imaging techniques to find and maintain the operating head of the catheter at a position in the body adjacent the volume of tissue to be diagnosed or treated.

FIG. **9** shows a variation on the steerable catheter system of FIG. **8**, wherein the internal imaging system can be operated to provide a 360° view around the circumference of the distal end of the catheter.

FIG. **10** shows a steerable catheter system in which an expandable, rotatable abrasive member actuated by an external magnetic field is used as a device for removal of plaque from the interior of blood vessels.

FIG. **11** shows a steerable catheter system suitable for computerized positioning control, that is actively positioned using an externally-applied magnetic field.

FIG. **12** shows a steerable catheter system suitable for computerized positioning control including an extendable, rotary member supporting a drug injection assembly.

FIG. **13** shows a catheter system suitable for computerized positioning control including a steerable drug injection mechanism actuated by micromotors.

FIG. **14** shows a catheter system (optionally, steerable under computer control) having a multidose drug delivery system.

FIG. **15** shows a cross-section of the catheter including the multidose drug delivery system shown in FIG. **14**.

FIG. **16** shows a steerable catheter having a telescoping stylet suitable for the controlled delivery of RF energy to surrounding tissue.

FIG. **17** shows a cross-section of the steerable catheter of FIG. **16**.

SUMMARY OF THE INVENTION

My invention provides a system and method for real-time, interactive computer control of the position of catheters, laparoscopes and/or endoscopic devices, enabling surgical personnel to exercise more precise control over the location of such devices. Novel methods of steering such devices within the body, and of delivering aliquots of drugs to precise, selected locations within the body also are disclosed. In addition, devices for the burning or ablation of surrounding tissue (as for example, during angioplasty procedures) are disclosed.

It is an object of this invention to provide a method of precise, real-time computer control of medical instrument or catheter position within the body, preferably using a feed-forward backpropogation neural network or a Hopfield neural network, capable of unsupervised learning, to observe the path of catheter introduction and learn the appearance of the surrounding tissue (and the appearance of the desired location using, for example, a Kohonen feature map) during the catheter introduction procedure; and to control the

position of the catheter thereafter despite ongoing changes in the shape and appearance of surrounding tissue.

It is a further object of this invention to provide improved steerable catheters whose shape can be changed within the body.

Still another object of this invention is to provide steerable catheters having minimal or no interior steering equipment, thus minimizing their size and therefore trauma to a patient.

It is another object of this invention to provide steerable catheters and the like equipped with controllable drug-dispensing devices.

It is yet another object of this invention to provide a steerable catheter capable of viewing internal tissue and structures within the body.

These and other features, objects and advantages of my invention will be apparent upon consideration of the following detailed description of my invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Computer Positioning Control

The present invention can employ imaging and computerized image analysis techniques based on sensors located external to the body (such as X-rays or Magnetic Resonance Imaging (MRI) sensors); images and coded image information derived from visual electrooptical sensors placed inside the body through a lumen of the catheter, or a combination of both types or still other of sensing systems or techniques. A variety of computer control systems can be used; one example appears in FIGS. **1** through **3**.

The present invention will be described in terms of controlling a catheter, but it will be understood by those of ordinary skill that endoscopes, laparoscopes, surgical instruments and other devices for insertion into the body of a patient also can be used.

Generally speaking, the location coordinates of select tissue of a living being in which a catheter-based operation is to be performed, are defined or computed with respect to images of the patient's anatomy showing anatomical structures which may be generated, for example, by employing computerized axial tomography (CAT scanning), magnetic resonance imaging (MRI), ultrasonography, positron emission tomography (PET), infrared, X-ray or microwave imaging, or other types of electronic scanning from sensors placed outside the body. In accordance with the present invention, a computed image of a select anatomical area is generated by using one or more of the conventional imaging modalities mentioned above, and a location coordinate with respect to a patient support structure is assigned to each pixel making up the image. The anatomical region into which it is desired to perform a catheterbased operation, such as injection of a drug, is then located on the electronically generated image or images by a radiologist, for example, with selected of the pixels making up the image of the region serving to define the transplant location. A preferred means by which this can be performed is to display the images of the catheter and the select anatomical region of the body on a display monitor having a manually positionable cursor for outlining an area containing the desired anatomical region. The operator of the system then inputs to a computer, digital data in the form of codes defining the anatomical location at which an operation is to be performed, as represented by the select pixels within the outlined area. As described below, each pixel of the body or organ image displayed by the computer has assigned to it a set of location coordinates calculated or defined with respect to a structure such as a table supporting the patient while the imaging is performed (see FIGS. **2** and **3**, discussed below). The same or a similar patient support structure is then utilized during the catheterization procedure. The catheter is moved manually or by the manipulator under computer control, inserted into select tissue, and operated so as to perform the desired operation at select location coordinates with respect to the support structure.

To facilitate use, crosshairs may be projected onto the screen and a mouse or other pointing device may be used to provide positioning instructions. When used with catheters containing fiber optic bundles (see below), one or more strands of the bundle may be used to project a beam of laser light onto surrounding tissue for aiming purposes, while the remaining fibers are used to transmit images.

To facilitate pinpointing of the catheter position, a variety of devices may be used depending on the sensing modality. In the case of ultrasonic sensing, for example, a closed cavity in or near the distal end of the catheter (or at some other location along the length of the catheter that must be pinpointed with precision) acts as a resonator to make the location appear clearly on the ultrasonic image. In the case of X-ray or MRI sensing, metal foil inserts or electronic circuitry can serve the same function. Active RF antennas also can be included at the desired point(s) inside the catheter.

In one embodiment the patient is required to be in the same position with respect to the support structure during both the imaging and catheterization procedures, so that the location coordinates selected will correspond to the proper anatomical region of the patient. One way of accomplishing this is to use a patient support structure having a moldable support structure defining a surface that can be made to conform to the shape of the patient's body as a kind of body cast. Once such a body impression is made, the patient may be placed in substantially the same position on the support structure for both scanning/imaging and subsequent transplantation procedures. Such a moldable patient support may also serve to immobilize the patient during both procedures. Other patient restraint devices, such as straps and adjustably positionable table stops, may also be employed.

The manner of assigning location coordinates to each image pixel depends on the particular imaging modality. For example, with a conventional CAT scanner, the x-ray tube emits a narrow beam of x-rays toward the patient with an x-ray detector, such as an array of scintillation detectors, positioned on the opposite side of the patient on which an x-ray shadow is formed. The x-ray tube and detectors, mounted on a rigid gantry, are rotated in multiple steps about the body until an entire axial slice is viewed from multiple angles. Codes defining the date acquired by the scintillation detectors are entered into a computer which uses mathematical algorithms to reconstruct a cross-sectional image or images of slices of the region examined. Such a computerized scanning arrangement calculates the degree to which the tissue interposed between the x-ray tube and the detectors absorb the x-ray beam and thereby provides an attenuation coefficient for each area of tissue examined. Essentially, the quantity of x-ray absorbed in small volumes (voxels) of body tissue in the slice is computed. Computer analysis of the image signals and data collected then allows assignment of a numerical value to each small area (pixel) of the cross-sectional plane. By means of a digital-to-analog converter, the numerical value of each pixel is translated to a gray scale for driving a CRT display or the like and may be employed for automatic control.

Due to the nature of the CAT scanning image reconstruction algorithm, the computer necessarily must assign location coordinates to each pixel with respect to the x-ray detector in order to generate the displayed image. Such coordinates are computed with respect to the patient support structure in the axial plane which is being imaged. In order for such coordinates to be useable for properly directing a transplantation or other tool in accordance with the present invention, however, they must be scaled and combined with another coordinate along the axial axis. In order to assign an axial location coordinate with respect to the patient support structure for each pixel, the positions of the x-ray tube and detector with respect to the patient support surface are sensed, and digital signals are generated that are input to the computer during the imaging procedure. The location coordinates for each pixel making up the image with respect to the patient support structure may be then readily calculated.

In pulse-echo ultrasound techniques, an ultrasonic pulse is transmitted through the body tissues with the reflected echoes from each acoustical interface sensed by a transducer in order to provide a train of digital signals that define an image of the underlying structure. In so-called B-mode ultrasound, the pulse-echo procedure is performed in scanning manner to provide signals for imaging the underlying morphologic structures in a tomographic format. The resulting scanning signals, after digitization, are used by electronic circuitry to construct a two-dimensional array of pixel values for driving a display. In order to construct an image, each pixel is assigned a coordinate location with respect to the transducer in the same plane at which the ultrasound is emitted. Conventional ultrasonic scanning, however, requires that the ultrasonic transducer be contacted or coupled to the body surface over the region to be examined and positioned so as to scan at various angles. In order for the computer to compute the location coordinates for each pixel making up a display of an ultrasonic scan, the transducer is mounted on a movable arm having sensors in its joints for producing signals proportional to the degree of flexion or rotation of each such joint, which sensors generate signals that are then fed to the computer for calculating the arm's position and orientation. Using appropriate scaling factors, the location coordinates for each pixel making up the image with respect to the patient support means may be readily calculated by a computer supplied with the above-mentioned data.

Computerized image construction in conventional MRI scanners, for employment in the present invention, is similar to that used in CAT scanners in that intensity values for an array of pixel values are computed with each pixel value stored in the computer being assigned a set of location coordinates in order to generate the reconstructed image. In MRI scanning, nuclei such as protons are subjected to a magnetic field gradient, called the slice-select gradient, which varies along the axis perpendicular to the plane of the image. Certain protons (such as hydrogen nuclei of water molecules in the tissue being scanned) within the magnetic field gradient are excited to resonance by a so-called 90 degree RF pulse which causes them to emit detectable radiation. The amplitude and frequency of such emitted radiation is used to assign proton density values to pixels and generate the MRI image. The location coordinates of each pixel in the image are calculated with respect to the patient support structure within the plane of the image cross-section, assuming the receiver coil of the MRI scanner remains at a fixed distance from the patient support structure. In order to derive an axial coordinate value (i.e., along an axis perpendicular to the plane of the cross-sectional image) for each pixel, it is necessary for the computer to compute the distance along the slice-select gradient with respect to the patient support structure, where the Larmor frequency of the excited nuclei corresponds to the frequency of the 90 degree RF pulse. Such a computation only requires that the computer be supplied with data reflecting the magnitude of the slice-select gradient field versus distance and the frequency of the RF pulse which can either be assumed to be in accordance with computer command or can be sensed by magnetometers and a separate RF receiver coil. MRI scanners also allow the particular gradient fields to be generated along arbitrarily chosen axes so as to produce images no only in the transverse plane but also in coronal, sagittal, and oblique planes. The axial coordinate for each image is then computed in the same way as just described, but the coordinate is then along an axis perpendicular to the plane of the cross-sectional image. Finally, since the patient support structure and the MRI imaging apparatus are relatively moveable with respect to one another, the computer is fed with data produced by position sensing means so that the location coordinates can be translated so as to be with respect to the patient support structure.

Once the location coordinates defining the select body region at which it is desired to perform the catheterization operation have been calculated by the computer, the catheter is inserted (either manually by surgical personnel or under computer control by robot manipulators) and the catheterization operation (for example, select drug injection) is performed. The process may then be repeated at different sites in the select body region. As will be described more fully below, electro-optical sensing and monitoring means may be provided, allowing the effects of the catheter operation to be monitored by the computer and the results of such monitoring may be used to control further injections.

FIG. **1** shows a computer system **10** for effecting the automated performance of a catheterization procedure in accordance with my invention. The catheter may be automatically positioned with respect to the patient by means of a multiple axis electro-mechanical manipulator which is controlled in its operation by coded control signals generated as a result of scanning that portion of the patient's body where it is desired to effect the particular catheter operation such as angioplasty, drug delivery or other operations. A catheter may be similarly directed under computer-control to an intraductal or other internal body site. Alternately, the catheter may be introduced manually using any of a number of known techniques including Seldinger insertion or the use of a split-sheath introducer, with the aid of control signals generated by the computer analysis of a real-time computer image of the location and path of the catheter, or its operating end or head.

The scanning signals may be generated by one or more known scanning devices, such as a nuclear magnetic resonance (NMR or MRI) scanning system, a computerized axial tomography (CAT) scanning system employing x-ray scanning, a PET scanning system, various infrared scanning systems operable to generate image signals of tissue and bones, or ultrasonic pulse-echo scanning systems. Such scanning signals may be computer processed and analyzed to generate multiple cross-sectional views such as parallel slice images of the portion of the body where it is desired to operate. The image information defined in the cross-sectional views or slices of the body tissue may be digitized to generate trains of digital (picture) signals which are analyzed by a computer wherein resulting code signals are generated defining the borders of the anatomical structures and which may be further computer processed to provide

further code signals indicative of coordinate locations of those structures. Such coded information may be used by the computer to control the operation of an automatic multi-axis manipulator for a catheter device, such as a heated scalpel, a hollow needle or ablation device, a rotary cutting tool, etc., to automatically position and insert the catheter, guide it to pass through intervening tissue or body ducts to reach the specific location where the catheterization operation is to be performed. Alternatively, the computer control system may simply observe the manually-controlled passage of the catheter to the desired location, using the scanning system.

Advantageously, a control algorithm utilizing a layered feedforward backpropogation neural network or a Hopfield neural network (or a combination of both) may be used. A Hopfield network, which can be arranged so as to be able to compare the pattern of approach to the desired location chosen by the surgeon and thereby "learn" the pattern of movement required to maintain the desired location against changes in position of the catheter or the patient caused by breathing, muscle contraction, etc. By minimizing the Hamming distance between the actual location at a given time and the "learned" location set by the surgeon during introduction of the catheter, the computer control system can effectively maintain the catheter position despite ongoing changes in the image of the location caused by physiological changes in the patient's tissue during the catheterization procedure.

System **10** includes a number of computers, devices and subsystems which are automatically controlled in their operation or generate feedback information in the form of signals passed through a control computer or microprocessor **11**. (Preferably, such feedback information is processed using an appropriate backpropogation function and presented to the output layer and/or the hidden layers of a neural network used to control catheter position.) An image analyzing computer **14** with an attendant programmable memory **15** analyzes image information generated by an NMR or CAT scanning computer **16** with attendant memory **17** which receives digitized image information from a plurality of MRI sensors **25** which can scan or sense a select portion of the body of a patient held immovable against a patient support or table **22** which is motorized and driven in multi-axis movement by a plurality of gear motors **23** (see FIG. **2**), the controls **24** of which are operated by trains of digital control signals passed through microprocessor **11** from either manual controls and/or one of the computers connected to the microprocessor. In addition, patient positioning motor assemblies **45** and **46** may be directly coupled to specific portions of the patient's body as shown in FIGS. **2** and **3**, allowing particular parts of the patient to be moved relative to the patient support **22** to further provide fine positioning of the patient relative to the sensor and catheter. Again, one or more neural networks designed for unsupervised training may be used to evaluate and weight the effects of moving the patient support **22** in comparison with the effects of moving the patient himself using motor assemblies **45** and **46**. With this approach, the computer progressively learns how best to maintain catheter position during the procedure by altering the weights used at each layer of the neural network as the catheterization procedure progresses.

Conventional CAT and MRI scanning arrangements generally rotate and axially move the patient through the scanning field. In addition, the MRI, CAT, PET body scanners or array of sensors **25** may also be supported on a mount **41** which is driven by motors **47** and **48** and controlled to move about and/or along one or more axes by means of a computer, such as a decision computer, connected to the microprocessor and operable to analyze the signals output by one or more of the computers **14** and **16** to effect control of the treatment operation and/or at least a portion of the scanning operation. The analog image signals output by the body scanners are converted to trains of digital image signals by one or more analog-to-digital converters **26** which pass such trains of signals through microprocessor **11** to the MRI or CAT scanning computer **16** for analysis and conversion to useable image information for use by the image analyzing computer **14**.

In the preferred embodiment, a catheter positioning manipulator **27** is supported adjacent the patient support **22** to which it is preferably connected. The catheter positioning controller/manipulator **27** is driven by a plurality of gear motors or hydraulic or electromechanical positioners (not shown) which are used to manipulate the proximal end **50** of the catheter outside the insertion point **54**, thereby affecting the location of the distal end **53** of the catheter. As more fully described below, such manipulation of catheter may include simply movement of the proximal end of the catheter; it may also include manipulation of the catheter shape within the body using various types of steering mechanisms.

As in the case of the patient positioning devices, one or more neural networks designed for unsupervised training may be used to evaluate and weight the effects of moving the patient support **22** in comparison with the effects of moving the proximal end of the catheter; manipulating the steering mechanism (if any) by using catheter steering controller **51**; and moving the patient himself using patient positioning motor assemblies **45** and **46**. With this approach, the computer progressively learns how best to maintain catheter position during the procedure by altering the weights used at each layer of the neural network as the catheterization procedure progresses.

The control signals generated thereby are sent to a bank of controls **28** which receive and pass direct command control signals from the computer **20** and apply feedback signals from the various manipulator motors to effect a suitable degree of precision operation of the catheter while its operating head is in alignment with select tissue to be treated or operated upon.

As described more fully below, a sensor or sensor array **33** may be located in the catheter at or adjacent its distal end **53** and may be operable to receive light reflected from tissue adjacent the end of the catheter. An optical fiber light pipe may extend from the output of the laser **31** through and to the open end of the catheter to conduct laser light to tissue adjacent the open end of the catheter while a second optical fiber may extend from such open end, back up another light pipe in the catheter to the sensor **33**. Resulting spectral radiation emitted by the tissue intersected by the laser radiation is passed to the end of the optical fiber adapted to receive same and back along such fiber to the photodetector at the other end thereof which generates an analog electrical signal modulated with spectral information relating to the tissue intersected by the laser light. Spectral information such as Raman spectra can be used to analyze and detect or diagnose the tissue and to distinguish plaque deposits from healthy tissue at the walls of blood vessels, for example.

Also shown connected to the control computer or microprocessor **11** via an interface **36** is a computer **35** such as a workstation or PC which includes a display and a keyboard which is operable to input data to the RAM **12** or any of the computers **14**, **16**, and **18** or to control the operation of the manipulator **27**, pump motor **38** and laser **31** or a plurality of such subsystems and devices for performing the described

treatment or surgical operations. It is noted that the pump **29** may be varied in its operation in accordance with the control signals generated by the decision computer **20** to a controller for such motor to predetermine the quantity and rate of flow of transplant medium and/or medication pumped to the injector **29A** after its injection tube or tubular needle has been driven under computer control to a select location with respect to select tissue. A plurality of pumps, such as pump **29**, may be operated by respective pump motors and may be provided mounted on the operating head of the manipulator, each of which pumps is operable to force flow a different medical material from a respective of a number of reservoirs to the needle or tube of the injector **29A** or to separate injectors therefor.

System **10** may also be operable to automatically perform auxiliary or other operations on select tissue, such as select tissue manipulation, handling, or cutting operations using one or more automatically positioned and controlled tissue grippers or cutting tools which are supported by the operating head of the manipulator **27** and controlled in powered operation to cut select tissue while gripper held or employing one or more lasers to ablate, burn or otherwise operate on such select tissue. RF energy also can be applied for such purposes, as described below.

Not shown, but assumed to form part of the computer **35** and its peripheral controllers, are manual means for effecting selective control of the described catheters, manipulators and the body tissue scanning devices, for use by medical personnel in supplementing the computer controlled operations in the performance of certain operations to detect and treat select tissue of the body. Computer controlled imaging and radar and laser range finding devices may also be employed to provide scanning signals for computer **14**, to permit the computer to further analyze the image content defined by select cross-sectional views or slices generated by the CAT, PET or MRI scanning system **25**, so as to automatically determine the depth location and three dimensional shape of the transplant site or a growth or growths thereat and to provide coded control signals for effecting automatic surgery on select tissue or treatment, as described. Thus the body scanning system **25** may be employed by itself to generate computer analyzable image information or may be supplemented with image information generated by an electronic camera, such as a television camera and/or by one or more laser-photodetector scanning arrangements which are fixedly supported within the catheter or which show a view from the distal end of the catheter through a fiber optic bundle.

As noted above, feedforward backpropogation or Hopfield neural networks (or a combination thereof) can be employed from the beginning of a catheterization procedure to "learn" the proper location of the catheter with respect to adjacent tissues and to continuously maintain that position against changes in position and sensed appearance of the surrounding tissue that may be caused by patient respiration, movement, and by the catheterization procedure itself.

Steerable Catheters

FIGS. **4** through **7** and **18** illustrate several catheter steering mechanisms designed to control the shape of the catheter inside the body. Conventionally, this is accomplished by tensioning and relaxing mechanical pull wires. Such arrangements, however, provide a limited range of shapes and typically can bend at only one predetermined inflection point along the length of the catheter. The devices disclosed below overcome those disadvantages.

Referring initially to FIG. **4**, a medical instrument such as a catheter **60** having one or more internal lumens **61**, is shown as containing one or more pull wires **62** affixed to a plate **63** near the distal end of the catheter. The lumen also may contain one or more of any number of operating mechanisms **64** (an extendable hollow needle **65** is illustrated, but many other operating mechanisms can be used), including such devices as biopsy devices, microwave or RF waveguides, chemical sensors and the like). Also included inside the lumen **61** is a controllable stiffening member **68**, which may take the form of a longitudinally-extending tube having one or more longitudinally-extending compartments **69** separated at intervals by walls **70**. Inside each compartment is a quantity of an electrorheological gel (ER gel), which is a gel that exhibits a phenomenon called the Winslow effect, or a magnetic gel, such as ER gel or fluid materials typically comprise a dielectric fluid in which is dispersed a plurality of microscopic electrorheologically sensitive particles. Application of an electrical field to such a composite material alters the pattern of electrical charge distribution on the surface of the electrorheological particles, causing them to be attracted to each other and to become aligned in a regular fashion, effectively forming chains of microscopic fibers between the electrodes. The electrorheological particles may include silica, starch, carboxy-modified polyacrylamides, and similar materials which will function only in the presence of some water. Other materials such as organic semiconductors, including silicone ionomers, are capable of functioning as ER gels without water. See, for example, U.S. Pat. No. 4,772,407 (Carlson); U.S. Pat. No. 5,032,307 (Carlson); U.S. Pat. No. 5,252,249 (Kurachi, et al); U.S. Pat. No. 5,252,250 (Endo, et al); and U.S. Pat. No. 5,412,006 (Fisher, et al), the disclosures of which are incorporated by reference herein. Melted chocolate also has been shown to exhibit ER gel properties.

When exposed to an electrical potential gradient, ER gels exhibit a macroscopic change from liquid-like behavior to essentially solid behavior. That is, the ER fluids or gels change from behaving as Newtonian fluids, which deform continuously and without limit in response to the application of any stress (force) at all, to Bingham plastic fluids, which will not deform at all until some threshold level of yield stress (force) is applied. The yield stress is often very high, resulting in the gel exhibiting essentially solid behavior.

Inserted into each compartment **69** of stiffening member **68** is an activating electrode **71**. The compartments may share a common ground electrode **72**, or separate pairs of electrodes may be used in each compartment. In either case, when an electrical potential is applied through wires **66** from controller **67** across any given compartment, the ER gel in that compartment solidifies (typically within a few milliseconds), thus making that portion of stiffening member **68** rigid. In that fashion the stiffness or pliability of each of the compartments **69** of stiffening member **68** can be electrically controlled. Thus, any portion of the length of the catheter can be made stiff or pliable, as desired. This changes where the catheter will bend in response to the off-center forces imposed by pull wires **62**. In this fashion the shape of the catheter can be changed as desired, producing one or more straight sections and one or more bent sections. Further, when the desired curvature has been attained, all compartments of the stiffening member **68** can be electrically energized, thus "freezing" the catheter in the desired shape for as long as the electrical potential is applied. Such electrical control technique used by the ER gel in this type of catheter makes it particularly attractive for use in combination with a computer-controlled positioning system of the general type shown in FIGS. **1–3**, above.

FIGS. **5** and **6** illustrate an alternative embodiment of a steerable catheter using ER gel. In this embodiment, the stiffening member **68** is formed as a full or partial annular space along the interior wall of the lumen **61**. In many instances this may be a preferable arrangement from the standpoint of conserving interior space and reducing the size of the catheter.

FIG. **7** illustrates an alternative mechanical steering arrangement, specifically designed for administration of drugs. In this design, a hollow needle **70** is attached to the distal end of a line of universally rotatable members **81**. (Any form of fluid-tight, universally rotatable member can be used; the preferred arrangement is the ball and socket joints depicted in FIG. **7**.) The ball and socket joints are hollow, providing a continuous fluid-tight passageway **82** through the center of the line of ball and socket joints. (One specific structure for such ball and socket joint fluid conduits is explained in U.S. Pat. No. 5,449,206 (Lockwood), the disclosure of which is incorporated by reference herein.) At intervals along the length of the line of ball and socket joints, pull wires **83** and **84** are attached to the exterior of the joints. Preferably four sets of pull wires are used, as shown, providing the ability to steer the line of ball and socket joints in any direction. Further, additional pull wires may be affixed at more than one longitudinal location (also as shown), which provides capability of bending the line of ball and socket joints at different longitudinal positions.

Still further, a plurality of optional pin and slot arrangements **85** can be used to prevent the individual ball and socket members from rotating with respect to each other. (The pins **86** are attached or molded to the exterior surfaces of the smaller or male balls **87** and protrude through slots **88** in the larger or female sockets **89** in the adjacent members.) The pin and slot arrangements permit the line of ball and socket joints to transmit torque; and also prevent the pull wires from becoming tangled since the individual members cannot rotate with respect to each other.

Another feature of the device shown in FIG. **7** is a rupture disk **90** which blocks the distal end of hollow needle **65**. The purpose of the disk is to prevent the flow of body fluids back into the passageway **82** during introduction of the catheter. This discourages clot formation and eliminates the need to flush the passageway with heparin or some comparable anti-clotting agent. The rupture disk **90** is designed to rupture when exposed to sufficient fluid pressure through passageway **82**, permitting flow of the liquid drug into the select area of tissue. (Alternatively, disk **90** may be a low melting point material that is opened by application of electrical resistance heat or laser energy thereto.)

Still another alternative to the use of an extendable hollow needle is a fluid jet injection system, which uses the high velocity of the fluid itself to penetrate tissue.

Steering systems of the foregoing types require internal pull wires or other internal structures, which occupy space within the lumen of the catheter. Desirably, however, the catheter diameter should be as small as possible to minimize insertion trauma and unwanted damage to surrounding tissue.

FIG. **11** illustrates a steerable diagnostic imaging catheter that works without any internal steering mechanism. The walls of the catheter include a plurality of compartments which include ferromagnetic materials or strong magnets or, more preferably, wound electromagnets. A patient who is to receive this catheter is placed inside a strong, controllable electromagnet. Once introduced into a patient, the position of the catheter can be adjusted by varying the direction and magnitude of the externally-applied magnetic field, thus pulling the catheter in any desired direction within the patient's body. If small electromagnets are used in the catheter walls themselves, only a desired part of the catheter length can be made responsive to the externally-applied magnetic field, thus making it possible to selectively shape the catheter inside the patient. Alternatively, a single annular magnet or piece of ferromagnetic material can be moved longitudinally along the interior wall of the catheter to alter the point of application of the external electromagnetic force.

The catheter of FIG. **11** also includes a lens **91** transpiercing the wall of the catheter and a plurality of fiber optic cables **92** operably attached to the lens, to transmit images or visual information back to external sensor **93** located outside the body. Visible light or laser energy also can be transmitted through the optical fibers for purposes of illumination and/or ablation of select tissue such as cancerous tissue and tumors. A flushing nozzle **94** supplied through a lumen **95** may be used to keep the lens **91** clear, if desired, by flushing with saline or some other benign, inert clear fluid, under computer control. (various specific optical fiber arrangements are known in the art, as shown for example in U.S. Pat. No. 4,967,745 (Hayes, et al.), the disclosure of which is incorporated by reference herein.)

Because of the need for controllable magnetic fields for catheter positioning in this embodiment, MRI imaging techniques may be unsuitable unless MRI imaging and catheter position are conducted intermittently. Ultrasonic imaging, of course, can be used. A cavity **96** can be provided in the distal end of the catheter to provide an enhanced ultrasonic image of its location.

In the treatment of certain conditions such as cancerous tissue, the local application of heat has been found desirable. Eddy current heating of a catheter having a positionable insert made of ferromagnetic material can be used for that purpose. A rapidly varying and/or focused external magnetic field is applied to cause the heating.

FIG. **8** illustrates a catheter using pull wire steering wires, which catheter has been adapted to carry a lens **91** and fiber optic bundle **92** alongside an operating mechanism **64** (in this instance an extendable hollow needle **65**). Such a catheter can be controllably positioned using a combination of external imaging and computer analysis of the images provided by lens **91** and fiber optic bundle **92**. It will be apparent to those of ordinary skill that the external magnetic steering mechanism or the ER gel steering mechanism described above also may be used in this type of catheter.

It may be desirable to be able to adjust the viewing direction of a fiber optic bundle at the distal end of a catheter. FIG. **9** illustrates one possible arrangement for accomplishing that goal. In this catheter, a rotatable mirror **101** driven by a micromotor **102**, is used to direct the axis or angle of view of a lens **91** in any desired direction out a clear window **97** in the wall of the catheter. A flushing nozzle **94** assists in clearing the surface of window **97**. Any of the steering mechanisms described above may be used with this arrangement of internals, as well.

A variety of procedures including angioplasty require the ability to operate abrasion devices within blood vessels or other body ducts. Typically this requires insertion of drive mechanisms through the lumen of a catheter. FIG. **10** shows an alternative arrangement in which a catheter **60** is fitted with a rotary abrasion member **111** mounted on central axle **112** and having an abrasive outer surface **115**. Rotary abrasion member **111** is axially supported between the distal

end **53** of the catheter and internal support member **114**. Magnets **113** are mounted at either or both ends of the cylindrical rotary abrasion member.

In operation, after the catheter has been introduced and positioned, an intermittent or rotating external magnetic field is applied from electromagnets outside the patient's body. This field engages magnets **113** and turns rotary abrasion member **111**, causing the mechanical abrasion of surrounding tissue. Optionally, a lens **91** and fiber optic assembly **92** may be used to observe the operation. Further, a plurality of fenestrations **116** may be provided, transpiercing the rotary abrasion member **111**. Blood or body fluids (supplemented with a saline flush, if desired) may be aspirated through fenestrations **116** into lumen **117** of the catheter, carrying away particles of plaque or other abraded material. The saline flush can be supplied through another lumen **118** of the catheter, and out through fenestrations **119** in the distal end of the catheter. The general direction of fluid flow is shown by arrows **117***a* and **118***a*. This simple device offers positive mechanical abrasion with minimal trauma because of the small diameter of the catheter. Steering of the catheter can be accomplished using external magnetic fields as well, or one of the mechanical steering mechanisms disclosed above can be used.

In treating a variety of diseases, it is desirable to be able to apply controlled doses of therapeutic drugs to select tissue without exposing nearby tissue to the same drugs. Chemotherapeutic agents used in cancer treatment, which may be rather toxic, are one example.

FIG. **12** illustrates a catheter suitable for directing a measured aliquot of liquid drug to a specific target location in the body. In this design, a reservoir **120** containing a pre-measured aliquot of liquid drug is positioned near the end of catheter **60**. Reservoir **120** is attached to the distal end of an extendable member **121**, which is used to extend the hollow needle **65** into the tissue surrounding the distal end **53** of the catheter through an orifice **122**. Release of the drug from reservoir **120** is accomplished by rotating extendable member **121**, which releases a catch mechanism **123**, allowing a compressed spring **124** to expand, forcing piston **125** forward and discharging the drug through optional rupture disk **90**. Positioning of the catheter can be accomplished using the computerized positioning system described above, in conjunction with the pull wires **62** shown in FIG. **12** or another of the steering systems disclosed above.

FIG. **13** illustrates an alternate embodiment in which a hollow needle **65** is extended by a micromotor **130** operating on a gear line **131** on the exterior of reservoir **120**. Some control of the angle of insertion is achieved by micromotor **132**, which moves the distal end **133** of reservoir **120** up and down in the lumen **61**.

In some instances it may be desirable to be able to inject multiple doses of drugs without removing the catheter from the body. FIGS. **14** and **15** illustrate a device capable of providing a plurality of injections of individual aliquots of drug, which may have different compositions. This system uses a rotatable cylinder **140** containing a plurality of individual reservoirs **141**. Operation of the device may be similar to that of a revolving pistol. The rotatable cylinder **140** is rotated by pulling on a rotating wire **142**, which is wrapped around the cylinder and then passes over a block **143**, which leads wire **142** back toward the proximal end of the catheter. Each individual reservoir **141** is fitted with a rupture disk **90**, or other type of controllable valve preventing premature discharge of the drug. Extension of hollow needle **65** is accomplished by extendable member **121**, as in the embodiment of FIG. **12**. Discharge of the drug is accomplished by individual spring piston arrangements in each reservoir, like that shown in the embodiment of FIG. **12**. Any of the steering mechanisms disclosed above also can be employed, if desired.

As noted above, it may be desirable to apply RF or microwave energy to specifically identified select tissue areas. FIGS. **16** and **17** provide an illustration of such a catheter. In this catheter, steering is provided by a pull wire **62** in cooperation with a plurality of ER gel compartments **69**, as described above in conjunction with the embodiment of FIGS. **5** and **6**.

Inside the distal end **53** of the catheter **60** is an angulation mechanism **150**. It comprises a telescopically extendable stylet **151** which is controllably operable as a microwave or RF antenna. The stylet is extended out of insulating sheath **152** by a reversible gear motor or a micromotor **153** (solenoid). The direction of extension of the stylet **151** is controlled in part by one or more micromotors **154**, which are mounted on support grid **155** to provide angulation in any desired direction. Optionally, means (not shown) can be provided for also extending the insulating sheath as well as the conductive stylet. This helps protect surrounding tissue from the RF or microwave energy and further localizes the tissue destructive effect of such energy.

It will be apparent to those of ordinary skill in the art that many changes and modifications may be made while remaining within the scope of my invention. I intend to cover all such equivalent structures and methods, and to limit my invention only as specifically delineated in the following claims.

I claim as my invention:

1. A drug delivery system comprising:

a. a catheter with an exterior surface, a proximal end and a distal end and having at least one lumen with an opening at said distal end of said catheter;

b. a drug reservoir having a proximal end and a distal end situated inside said lumen adjacent said distal end of said catheter;

c. an extendable member connected to said proximal end of said reservoir;

d. a hollow tube connected to said distal end of said reservoir and communicating therewith, having a dispensing front end with an opening therein, a hollow needle being completely disposed and supported within said lumen and movable generally longitudinally through said lumen from a retracted position therein whereby the dispensing end of said tube does not protrude beyond the exterior surface of the catheter, to an extended position whereby said dispensing end of said needle protrudes through said opening beyond the exterior surface of the catheter so as to permit said dispensing end of said needle to penetrate tissue positioned against or in close proximity to the exterior surface of said catheter;

e. a force means for controllably moving said extendable member in a longitudinal direction to extend said needle;

f. a dispensing mechanism contained within said reservoir; and

g. release means for remotely power operating or triggering said dispensing mechanism.

2. The drug delivery system of claim **1**, wherein said dispensing mechanism comprises a spring-loaded piston.

3. The drug delivery system of claim **2**, further comprising a rupture disk situated inside said hollow needle.

4. The drug delivery system of claim 1 wherein said release means comprises a catch operated by rotating said extendable member.

5. The drug delivery system of claim 1, further comprising at least one pull wire for steering said catheter.

6. The drug delivery system of claim 1, wherein said dispensing mechanism comprises a motor-operated piston.

7. The drug delivery system of claim 1, wherein said dispensing mechanism further comprises: (a) a rotatable cylindrical housing containing a plurality of reservoirs; (b) an axle around which said cylindrical housing revolves; and (c) means for revolving said cylindrical housing to align said reservoirs with said hollow needle.

8. The drug delivery system of claim 7, wherein said means for revolving said housing is a pull wire wound around said housing.

* * * * *

US006052610A

United States Patent [19]

Koch

[11] Patent Number: 6,052,610

[45] Date of Patent: Apr. 18, 2000

[54] **MAGNETIC CATHETER TRACKER AND METHOD THEREFOR**

[75] Inventor: **Roger Hilsen Koch**, Amawalk, N.Y.

[73] Assignee: **International Business Machines Corporation**, Armonk, N.Y.

[21] Appl. No.: **09/004,834**

[22] Filed: **Jan. 9, 1998**

[51] **Int. Cl.**[7] **A61B 5/05**

[52] **U.S. Cl.** **600/424**; 324/207.11; 324/260

[58] **Field of Search** 600/407, 424; 128/899; 324/244, 260, 246, 247, 256, 259, 261, 207.11, 207.13, 207.17

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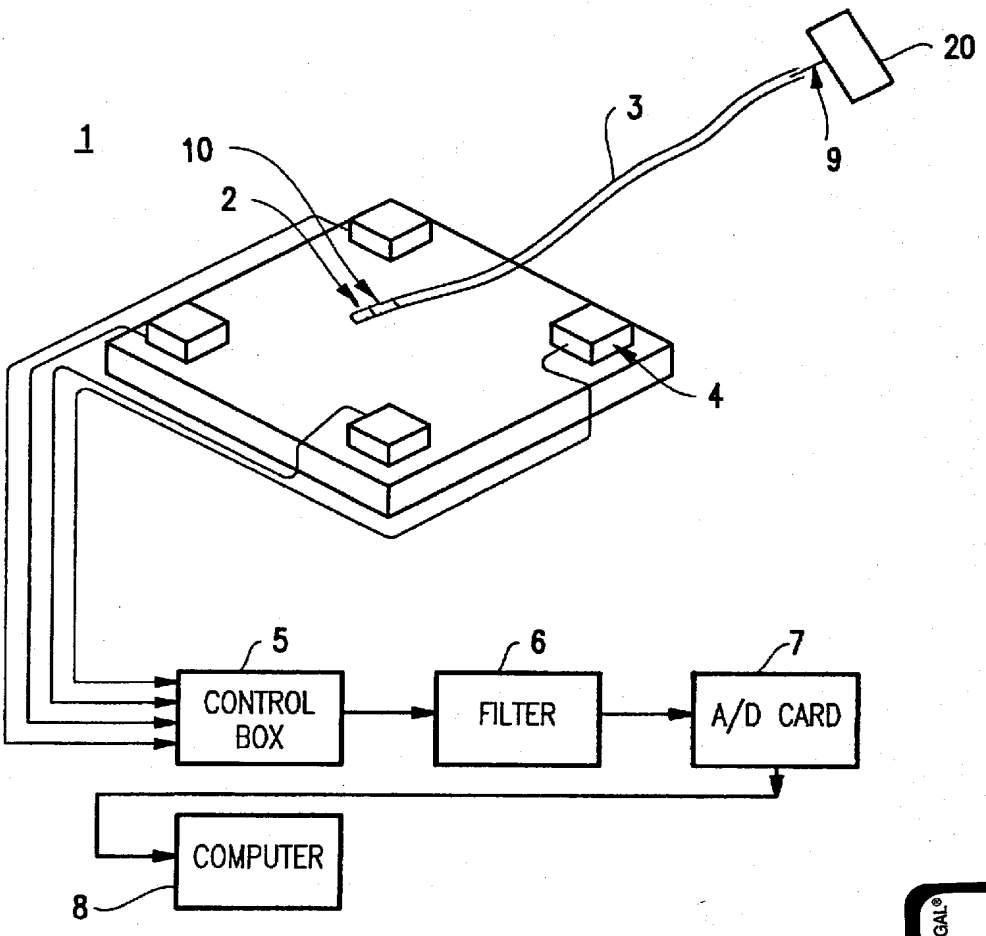
Primary Examiner—Brian L. Casler

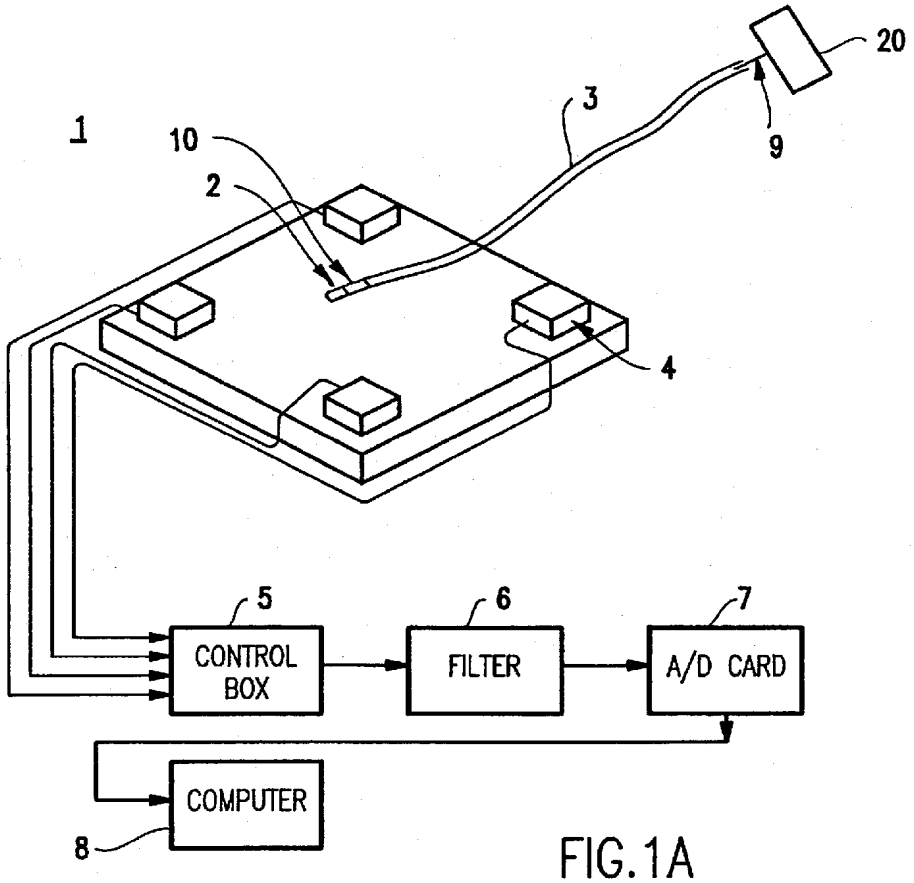
Attorney, Agent, or Firm—Whitham, Curtis & Whitham

[57] **ABSTRACT**

A method, apparatus, and system for tracking an object within a volume, includes coupling a rotating magnetic dipole to the object, measuring the magnetic fields either remotely, on the surface of, or exterior to the volume, to produce measurements; and based on the measurements, determining the position and the orientation of the magnetic dipole, thereby to determine a position and orientation of the object.

10 Claims, 3 Drawing Sheets




20
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6
7
CONTROL BOX
FILTER
A/D CARD
COMPUTER
8

FIG.1A

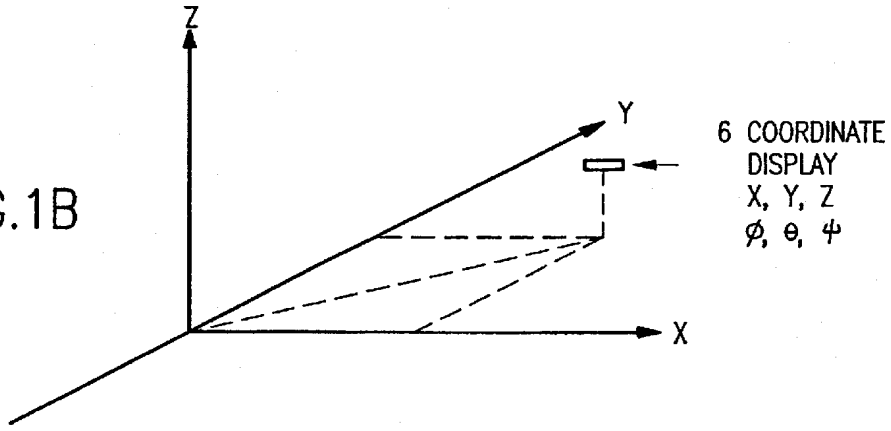
Z
Y
X
6 COORDINATE DISPLAY
X, Y, Z
ϕ, θ, ψ

FIG.1B

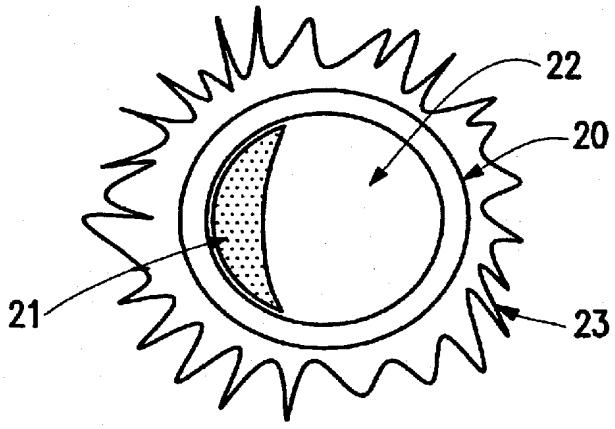

FIG.2

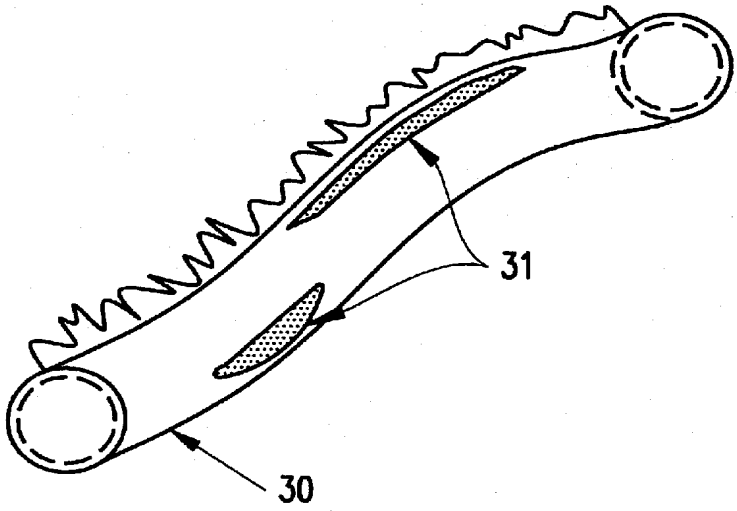

FIG.3

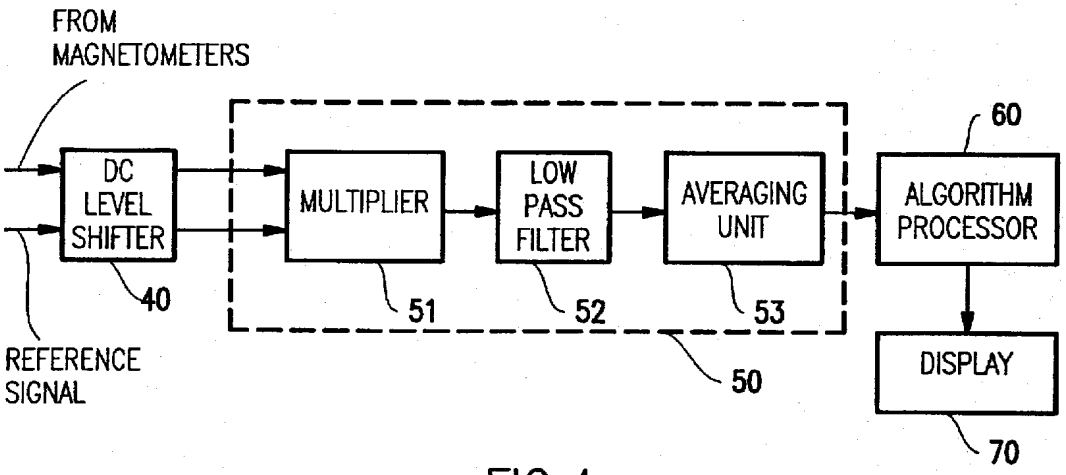
FROM
MAGNETOMETERS
DC
LEVEL
SHIFTER
40
REFERENCE
SIGNAL
MULTIPLIER
51
LOW
PASS
FILTER
52
AVERAGING
UNIT
53
50
60
ALGORITHM
PROCESSOR
DISPLAY
70

FIG.4

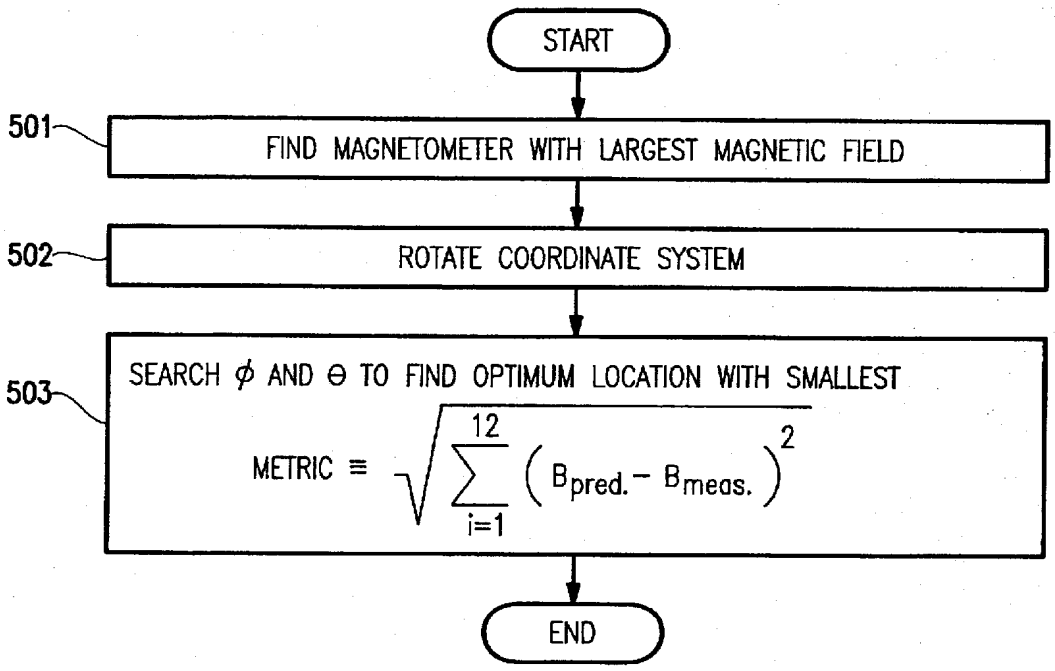
START
501
FIND MAGNETOMETER WITH LARGEST MAGNETIC FIELD
502
ROTATE COORDINATE SYSTEM
503
SEARCH ϕ AND Θ TO FIND OPTIMUM LOCATION WITH SMALLEST
METRIC $\equiv \sqrt{\sum_{i=1}^{12} \left(B_{pred.} - B_{meas.} \right)^2}$
END

FIG.5

MAGNETIC CATHETER TRACKER AND METHOD THEREFOR

BACKGROUND OF THE INVENTION

The present invention generally relates to a system, apparatus and method for tracking an object in a body or region, and more particularly to a system, apparatus and method for determining the position and orientation of a probe, such as a catheter, in a volume such as a human body by tracking the position of a rotating magnet or oscillating magnetic dipole that is placed in or on the probe or catheter.

DESCRIPTION OF THE RELATED ART

Generally, with the existing technology and techniques, it has been very difficult to locate in three dimensions an object in a three-dimensional volume. Most conventional systems use separate two-dimensional images of an area of interest. However, the exact relative positions of the separate images are unknown, because the accuracy of the conventional methods for determining the location of the images is poor. Hence, finding an object in a three-dimensional volume, such as a human body, has been difficult, if not impossible, with the conventional techniques.

In many surgical procedures, physicians must insert probes (e.g., catheters) into the human body, and later must detect the position of the catheters for additional treatment, investigation, manipulation, removal from the body, etc.

Typically, the positions of the catheters are measured using a simple x-ray imaging system such as a fluoroscope or the like. However, this system images primarily in two dimensions (e.g., as shown in FIG. **2**) and is incapable of indicating the exact angular orientation of the catheter around its long axis. Precise quantitative information of the position of the catheter in the three spatial dimensions and the three orientation angles would be of great benefit.

For example, when a physician uses an ultrasonic transducer mounted on the rotating tip of a catheter imager to image the plaque in a person's arteries near or around the heart, the physician receives a series of two-dimensional images from the ultrasonic imager as the catheter is pulled through the blood vessels. However, the exact relative positions of the separate images are unknown, because the accuracy of the present methods for determining the location of the images is poor and incapable of measuring the orientation angles of the catheter. In any application where catheters or instruments must be placed into or next to the human body in a medical procedure, precise quantitative information of the precise location and angle of each probe would be of great value.

Moreover, extending beyond the problem of tracking a catheter in the human body, there are many situations where measuring the exact position and orientation of an object using remote sensors would be highly beneficial.

SUMMARY OF THE INVENTION

In view of the foregoing problems of the conventional systems and methods as first recognized by the present inventor, an object of the present invention is to provide a system, apparatus and method for accurately tracking a probe (e.g., catheter) in a three-dimensional continuum by either utilizing a preexisting rotating motion of the probe (or by adding a rotating motion to the same), and attaching a small permanent magnet to the probe.

Another object is to provide a system, apparatus and method for accurately tracking the position a rotating ultrasonic catheter in a human body by using magnetic tracking.

In a first aspect of the present invention, an extremely small (e.g., approximately 1–2 mm^2) but powerful (e.g., on the order of about 10^{-2} $Amp \cdot m^2$) rare-earth magnet is positioned on a probe or the tip of a catheter.

With the present invention, the tip of the probe or catheter must rotate (or be made to rotate) around some axis. Such an alteration of the probe or catheter is inexpensive and relatively simple on those probes or catheters that already have such a rotating motion. Rotating motion could be added to those probes or catheters that do not already rotate (e.g., through a motor or the like), which again would be an inexpensive and simple retro-fit in many situations.

When the probe or catheter is in the volume or body of interest, magnetic field sensors placed around the volume, or next to the body, record the magnetic fields generated by the rotating magnet on the probe or catheter.

Using the outputs of the magnetic field sensors, mathematical algorithms and a computer/processor can determine the exact position and orientation of the magnet, and hence the exact position and orientation of the probe or catheter. This allows exact positional information to be recorded as the probe or catheter is moved.

For an ultrasonic catheter, the computer constructs a three-dimensional image of all the separate two-dimensional ultrasonic images obtained from the imager.

Thus, with the present invention, a magnet is attached to the tip of a catheter, and when this catheter is placed inside the body (e.g., blood vessels), magnetic field measurements exterior to the body can accurately determine the position and orientation of the magnet, and, hence the position and orientation of the catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, aspects and advantages will be better understood from the following detailed description of a preferred embodiment of the invention with reference to the drawings, in which:

FIG. **1A** is a block diagram illustrating a system for tracking an object according to the present invention;

FIG. **1B** illustrates a coordinate system for use with the present invention;

FIG. **2** illustrates a schematic, two-dimensional image of an artery from an ultrasonic imager;

FIG. **3** illustrates a schematic, three-dimensional image using the system and method according to the present invention;

FIG. **4** illustrates a schematic digital lock-in for a computer **8** according to the present invention; and

FIG. **5** is a flowchart of the steps of the process (e.g., an inversion method) for tracking the object in a body according to the present invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

Referring now to the drawings, and more particularly to FIG. **1A**, there is shown a block diagram of the system for tracking an object (e.g., such as a catheter) in a body (e.g., such as the human body).

As shown in FIG. **1A**, a system **1** is provided for tracking a magnetic dipole **2** attached to a first end (e.g., tip) of an elongated probe (e.g., a catheter in the exemplary application) **3**. For example, the magnetic dipole preferably includes a rotating permanent magnet. The magnet is preferably extremely small (e.g., approximately 1–2 mm^2) but

powerful (e.g., on the order of about 10^{-2} Amp·m^2) rare-earth magnet is positioned on a probe. While not as preferred for the present invention as the rotating rare earth magnet, it is conceivable that an electromagnet with a constant current, an electromagnet with an alternating current applied thereto, or the like could be used with suitable modifications, as would be known by one of ordinary skill in the art taking the present specification as a whole.

A second end of the catheter **3** is for insertion into a body of interest (e.g., a human body). The catheter **3** may have any diameter. For example, in one implementation, the catheter **3** has an outer diameter of 1 mm.

As shown in FIG. **1A**, the present invention measures the magnetic field at a plurality (e.g., two or more) of positions. The measurements are made with a magnetic sensing device (e.g., magnetometer) **4**, such as a SQUID, a flux gate, a magneto-resistive sensor, a hall probe, or the like. Preferably, a 3-axes magnetometer is used as the magnetic sensing device. However, configurations are possible with 1-, 2-, or 3-axis (or more) sensors. However, a sensor having 3 axes is preferred, with a 6-coordinate display being shown in FIG. **1B**.

In the implementation shown in FIG. **1A**, the magnetometers **4** are preferably mounted in the corners of a substrate or in other suitable positions based on operating characteristics and designer constraints.

It is noted that while four magnetometers are shown in FIG. **1B**, only two magnetometers are needed to localize the rotating magnet **2**. Hence, any configuration of stationary magnetic sensors could be used. An algorithm used by the present invention allows an arbitrary orientation, and/or positioning, but requires at least two magnetometers to be placed at different positions. As mentioned above, the magnetometers preferably comprise a three-axes magnetometer.

The outputs of the magnetometers **4**, representing the values of the magnetic fields, are provided to a control box **5** for operating the magnetometers. The control box **5** is available commercially, or alternatively may be constructed by one of ordinary skill in the art by assembling standard electronics for operating the magnetometers.

It is noted that there are three outputs for each magnetometer **4** (although only one is shown for convenience and brevity in FIG. **1A**). In other words, in the system as shown in FIG. **1A**, there are 12 outputs total, since there are provided four magnetometers **4**.

The outputs of the control box **5** are filtered by filters **6**. Specifically, a filter box **6** including a plurality of filters is for providing a band pass around the rotational frequency of the magnet, which helps reduce environmental noise signals from affecting the output of the tracker.

The output of the control box **5** represents the oscillating magnetic field that each of the magnetic sensors **4** is recording.

Filters **6** preferably comprise a band-pass filter at the rotational frequency of the magnet. Preferably, there is a filter **6** provided corresponding to each magnetic sensor **4**. Also, there can be a gain in the filter box electronics (e.g., typically a gain of about 10 to 100, but of course any gain can be provided depending upon the designer's constraints and requirements).

Thereafter, the output of the filters **6** is digitized by an analog-to-digital (A/D) converter **7**, in order to input digital values representing the magnetic fields into a computer (processor) **8**.

It is noted that a motor **20** is preferably provided for rotating the magnet **2**. The motor **20** also provides an AC reference synchronization signal (e.g., for synchronization with the magnet) to the A/D converter **7**. The motor **20** is provided on one end of the probe (catheter), and the magnet is provided on the other end of the probe, as shown in FIG. **1B**.

As mentioned above, a schematic two-dimensional image of an artery wall **20** from an ultrasonic imager (e.g., **10** as shown in FIG. **1**) is shown in FIG. **2**. Such a two-dimensional schematic is similar to that provided by the conventional systems and techniques. The artery wall includes plaque **21** formed thereon, thereby reducing the cross-sectional area of the artery for carrying blood **22**. Heart tissue **23** is shown surrounding the artery in this exemplary application.

In contrast to the schematic image of FIG. **2**, a schematic three-dimensional image using a rotating magnetic tracking (e.g., made possible by the rotating shaft **9** coupled to the catheter **3** as shown in FIG. **1A**) according to the present invention is shown in FIG. **3**. As shown, the positioning of the catheter is made much more accurate with the rotating tracking method and positioning of the catheter **3** in regard to an artery **30** and the plaque build-up **31** therein can be detected reliably and accurately.

As shown in FIG. **4**, the architecture of the computer **8** preferably comprises a direct current (DC) level shifter (subtractor) **40** to reduce the offset from zero of the average magnetic field, a digital lock-in unit **50** (preferably approximated in software for each of the input channels), and an algorithm processor **60** for performing the inventive algorithm, and specifically the inversion method discussed below, to select/provide a result. It is noted that, while the digital lock-in unit **50** preferably is approximated in software according to the present invention, the digital lock-in unit alternatively could be provided in hardware as would be known by one of ordinary skill in the art taking the present invention as a whole.

The digital lock-in is achieved by recording a reference signal from the rotating magnet synchronously with the rotating magnet **2**. The signals from the magnetometers and the reference signals are input to the DC level shifter **40**, as mentioned above, and then outputs are provided to a multiplier **51** of the digital lock-in **50**.

An output from the multiplier is provided to a low pass filter **52** and filtered. Thereafter, an averaging unit **53** averages the outputs from the low pass filter **52**, and provides an output. Typically, averaging unit **53** will provide 6–12 outputs (e.g., 3/magnetometer) depending upon the number of magnetometers. The outputs from the averaging unit **53** represents an estimate of the magnetic field from the respective magnets **2**.

Thereafter, the outputs are input to the algorithm processor **60** which selects a result based on an inversion method, as discussed below with reference to FIG. **5**. The result of the processor **60** is output to a display (e.g., cathode ray tube (CRT) monitor, printer, etc.) **70**, if desired. It is noted that the display **70** does not constitute a component of the architecture of the computer **8**.

Referring now to FIG. **5**, the inversion method performed by the algorithm processor **60** is described.

First, in step **501**, the magnetometer with the largest magnetic field is found based on the values (e.g., 6 to 12 values) provided by the averaging unit **53**. Such a process can be performed by comparing each of the values to one another and selecting the largest value, and storing the same.

Then, in step **502**, the coordinate system is rotated so that the vector field lies in two direction for that vector (e.g., see

the coordinate system of FIG. 1B). Using polar coordinates, only the ϕ and θ values are unknown.

Finally, in step **503**, the ϕ and θ values are iteratively searched to find the best location. The best location will be the value with the smallest "metric" (e.g., smallest deviation between the predicted field and the measured field). Thus, the metric represents the "goodness of fit". Specifically, to find the "metric", the following equation is used:

$$\text{metric} = \sqrt{\Sigma^{\cap\cap}} \left(B_{\text{L}\oplus\supset\text{C}} - B_{\text{J}\supset<\ominus}\right)^{\text{ll}}$$

The operation and tracking algorithm used by the computer **8** are described below.

In operation, the computer **8** (e.g., multiplier **51**) multiplies the input signal of each of the magnetic sensors **4** by a reference signal from the rotating magnet **2** to produce a dc level which corresponds to the average magnetic field for that sensor **4** at the rotational frequency. This concept is exactly that of a lock-in implemented digitally.

Thereafter, the output of the digital lock-in can be used with the inversion algorithm (e.g., inversion method), to convert the measured magnetic fields into the position of the magnet **2**.

Using the values of the magnetic fields at the measurement positions, the computer inversion algorithm converts the magnetic field values into a value representing the position of the magnet **2**.

Hereinbelow, one cycle of the operation of attaching the magnet to the catheter **3**, insertion of the catheter into the body, and then taking a measurement of the position of the catheter, is described.

The operation of the system is quite simple. First, the magnet is attached to the catheter, and then the catheter is placed into the human body. The catheter is normally rotated in order to make an ultrasonic measurement.

Then, the sensor platform holding the sensors **4** is placed near the body, and, by using the above described electronics and algorithm, the position of the rotating magnet, and hence the tip of the sensor, can be determined.

It is noted that, while such a measurement above may be made with the magnet affixed directly to the catheter, the technique according to the present invention works significantly better for catheters which allow the magnet to be attached to a rotating flexible shaft **9** within the catheter **3**. Such catheters **3** are typically used to image ultrasonically the insides of blood vessels and arteries around the heart or in the urinary track. Such rotation is made possible, for example, by the motor **20** mentioned above.

As mentioned above, the three-dimensional imaging provided by the rotating magnet tracking of the present invention is highly accurate as compared to the two-dimensional imaging of the conventional techniques.

Thus, rotating magnet tracking is advantageous in that it inexpensively provides instantaneous and exact positional information of the location of the catheter **3**. Such instantaneous and exact positional location is obtained without the need for an accurate dc measurement of the magnetic field of the hospital room before the catheter is introduced, as in a non-rotating source. Additionally, the rotating source tracking can be performed easily in an ordinary hospital environment.

ADVANTAGES OF THE PRESENT INVENTION

With the invention, costs are minimized since an extremely small rare earth magnet is positioned on a tip of a catheter which is an inexpensive and minimal alteration of the catheter.

Further, the reliability and accuracy of the measurement are high, as compared to the conventional systems.

While the invention has been described in terms of a single preferred embodiment, those skilled in the art will recognize that the invention can be practiced with modification within the spirit and scope of the appended claims.

Having thus described my invention, what I claim as new and desire to secure by Letters Patent is as follows:

1. A method of tracking an object within a volume, the method comprising steps of:

coupling a rotating permanent magnet to said object;

measuring magnetic fields produced by the rotating permanent magnet remotely or on the surface of or exterior to the volume, to produce measurements; and

based on said measurements, determining a position and an orientation of the rotating permanent magnet and a position and orientation of said object to which said permanent magnet is coupled comprising:

inputting said measurements to a processor, said measurements comprising signals representing values of the magnetic fields;

filtering said signals to produce filtered signals;

digitizing said filtered signals;

recording a reference signal from the rotating permanent magnet synchronously with the rotating magnetic dipole;

performing a direct current (DC) level shift of said digitized signals and the reference signal to reduce an offset from zero of an average magnetic field and produced a level-shifted value; and

performing a digital lock-in operation based on said level-shifted value.

2. The method according to claim **1**, wherein said digital lock-in operation comprises:

multiplying each of said level-shifted values by a reference signal from the rotating permanent magnet to produce a DC level which corresponds to the average magnetic field for a respective sensor at a rotational frequency to produce multiplied values;

filtering said multiplied values by a low pass filter; and

averaging said multiplied values having been filtered to provide average outputs, said average outputs representing estimates of the magnetic fields.

3. The method according to claim **2**, further comprising the step of processing to select a result, said step of processing comprising:

performing an inversion method, said inversion method comprising:

based on said multiplied values having been filtered, identifying a magnetic sensor having a largest magnetic field;

rotating a coordinate system of the magnetic sensor having the largest magnetic field such that a vector field thereof lies in two directions using polar coordinates, iteratively searching for a combination of ϕ and Θ values which provide a smallest deviation between a predicted magnetic field and a measured magnetic field so to convert the magnetic fields into a position of the rotating permanent magnet.

4. The method according to claim **3**, further comprising:

displaying said result on a display.

5. A system for tracking an object in a volume, comprising:

a rotating permanent magnet coupled to said object;

at least two detectors for measuring magnetic fields exterior to the volume produced by said rotating permanent magnet, to produce measurements;

a determining unit for determining, based on said measurements, a position of the permanent magnet and a position of said object to which said permanent magnet is coupled;

a bandpass filter for filtering outputs from said at least two detectors, thereby providing a band pass around a rotational frequency of the permanent magnet, a filter being provided corresponding to each said at least two detectors; and

an analog-to-digital (A/D) converter for converting filtered outputs from said filter to digital values representing the magnetic fields, said digital values being inputted into said determining unit, said determining unit comprising a computer.

6. The system according to claim **5**, further comprising:

a motor for rotating said magnet, and for providing an alternating current (AC) reference synchronization signal to said A/D converter.

7. The system according to claim **6**, further comprising:

a rotating shaft coupled to the object.

8. A system for tracking an object in a volume, comprising:

a rotating permanent magnet coupled to said object;

a detector for measuring magnetic fields exterior to the volume produced by said rotating permanent magnet, to produce measurements; and

a determining unit for determining, based on said measurements, a position of the permanent magnet and a position of said object to which said permanent magnet is coupled comprising:

means for recording a reference signal from the rotating permanent magnet synchronously with the rotating permanent magnet;

a direct current (DC) level shifter for shifting a level of said digitized signals and the reference signal, to reduce an offset from zero of an average magnetic field and produced a level-shifted value; and

a digital lock-in unit for performing a digital lock-in operation based on said level-shifted value.

9. The system according to claim **8**, wherein said digital lock-in unit comprises:

a multiplier for multiplying each of said level-shifted values by a reference signal from the rotating permanent magnet to produce a DC level which corresponds to the average magnetic field for a respective sensor at a rotational frequency, to produce multiplied values;

a low pass filter for filtering said multiplied values; and

an averaging unit for averaging said multiplied values having been filtered to provide average outputs, said average outputs representing estimates of the magnetic fields.

10. The system according to claim **9**, further comprising a processor for processing to select a result, said processor including:

means, based on said multiplied values having been filtered, for identifying a detector detecting a largest magnetic field;

means for rotating a coordinate system of the detector detecting the largest magnetic field such that a vector field thereof lies in two directions; and

means, by using polar coordinates, for iteratively searching for a combination of ϕ and Θ values which provide a smallest deviation between a predicted magnetic field and a measured magnetic field, so as to convert the magnetic fields into a position of the rotating permanent magnet.

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